

US3372005 (Prod: Palm Beach Research Center)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:16:55

All time stamps listed in this document are displayed in GMT

US3372005

Form: Participant Creation

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

Participant ID

US3372005

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

US3372005

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 17:31:14

Generated On: 09 Jun 2021 17:16:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 JUL 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

US3372005

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 17:31:13

Generated On: 09 Jun 2021 17:16:55

Date of Birth (MMM yyyy)	(b) (6) 1925
Age	94
Age Units	YEARS
Age (Derived)	94
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) 12 Feb 2021 17:31:13

Generated On: 09 Jun 2021 17:16:55

Date of Informed Consent (*dd MMM yyyy*) 31 JUL 2020

Month and Year of Informed Consent (derived) JUL 2020

Year of Informed Consent (derived) 2020

Protocol Version Amendment 1 ☒
Amendment 2 ☐
Amendment 3 ☐
Amendment 4 ☐
Amendment 5 ☐

Was participant enrolled in the study? Yes ☒
No ☐

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

If reason for screen fail is Other, specify _____
Was this participant screened previously? Yes ☐
No ☒

If Yes, previous participant number _____
Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 17:31:13

Generated On: 09 Jun 2021 17:16:55

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 17:31:14

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Feb 2021 17:31:13

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Condition	INGUINAL HERNIA - LEFT
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

US3372005

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Feb 2021 17:31:13

Generated On: 09 Jun 2021 17:16:55

Condition	OSTEOARTHRITIS LEFT KNEE
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

US3372005

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 17:31:13

Generated On: 09 Jun 2021 17:16:55

Condition	LEFT KNEE REPLACEMENT
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

US3372005

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Feb 2021 17:31:13

Generated On: 09 Jun 2021 17:16:55

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Feb 2021 17:31:13

Generated On: 09 Jun 2021 17:16:55

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

US3372005

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Feb 2021 17:31:13

Generated On: 09 Jun 2021 17:16:55

Condition	INGUINAL HERNIA - RIGHT
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Feb 2021 17:31:13

Generated On: 09 Jun 2021 17:16:55

Condition	LEFT INGUINAL HERNIORRHAPHY
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

US3372005

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 12 Feb 2021 17:31:13

Generated On: 09 Jun 2021 17:16:55

Condition	RIGHT INGUINAL HERNIORRHAPHY
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 16 Mar 2021 16:23:25

Generated On: 09 Jun 2021 17:16:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	31 JUL 2020
Time of assessment (<i>00:00-23:59</i>)	14:52 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 14:52
Height (<i>xxx.x</i>)	162.6 cm
Weight (<i>xxx.x</i>)	60.4 kg
BMI (<i>xxx.x</i>)	22.84525 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	36.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	58 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 17:31:14

Generated On: 09 Jun 2021 17:16:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 JUL 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) 12 Feb 2021 17:31:14

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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 94 YEARS OLD

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 17:31:14

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 17:31:14

Generated On: 09 Jun 2021 17:16:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 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) 16 Mar 2021 16:23:25

Generated On: 09 Jun 2021 17:16:55

What was the date of randomization? (dd MMM yyyy) 04 AUG 2020

What was the participant's randomization number? 184643

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) 12 Feb 2021 17:31:14

Generated On: 09 Jun 2021 17:16:55

Height	162.6 cm
Weight	61.2 kg

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 17:31:14

Generated On: 09 Jun 2021 17:16:55

Height	162.6 cm
Weight	61.2 kg
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 AUG 2020
Time of assessment (00:00-23:59)	12:25 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 12:25
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 17:31:14

Generated On: 09 Jun 2021 17:16:55

Height	162.6 cm
Weight	61.2 kg
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)	04 AUG 2020
Time of assessment (00:00-23:59)	13:50 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 13:50
Temperature (xxx.x)	36.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3372005

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 17:31:14

Generated On: 09 Jun 2021 17:16:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 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: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 17:31:14

Generated On: 09 Jun 2021 17:16:55

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) 4 AUG 2020

What was the treatment time? (00:00-23:59) 13:20 (24 HR)

Treatment Date and Time (derived) 4 AUG 2020 13:20

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) 12 Feb 2021 17:31:14

Generated On: 09 Jun 2021 17:16:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 AUG 2020
Collection time (00:00-23:59)	12:45 (24 HR)
Collection date and time (derived)	04 AUG 2020 12:45

US3372005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 17:31:14

Generated On: 09 Jun 2021 17:16:55

Collection date (dd MMM yyyy)			04 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:42	04 AUG 2020 12:42
Nasopharyngeal Swab 2	No		

US3372005

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:31:14

Generated On: 09 Jun 2021 17:16:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 14:06

PC Open Date & Time

04 AUG 2020 13:40

PC Close Date & Time

04 AUG 2020 16:10

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.8 °F

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

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

PC Time Stamp	05 AUG 2020 08:43
PC Open Date & Time	04 AUG 2020 17:05
PC Close Date & Time	05 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 09:26

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 08:28

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:55

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

97.8 °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

07 AUG 2020 20:51

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 19:20

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 20:51

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 20:18

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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

04 AUG 2020 14:07

PC Open Date & Time

04 AUG 2020 13:40

PC Close Date & Time

04 AUG 2020 16:10

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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

05 AUG 2020 08:44

PC Open Date & Time

04 AUG 2020 17:05

PC Close Date & Time

05 AUG 2020 11:59

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:55

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

06 AUG 2020 09:26

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:55

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

07 AUG 2020 08:29

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:55

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

07 AUG 2020 20:52

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:55

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

08 AUG 2020 19:20

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:55

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

09 AUG 2020 20:52

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:55

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

10 AUG 2020 20:18

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 14:08
PC Open Date & Time	04 AUG 2020 13:40
PC Close Date & Time	04 AUG 2020 16:10

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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

No ☒

Yes ☐

PC Time stamp	05 AUG 2020 08:45
PC Open Date & Time	04 AUG 2020 17:05
PC Close Date & Time	05 AUG 2020 11:59

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:55

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 ☒

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:55

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 09:27
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:55

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

51 of 2705

EAB) (1725)

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:55

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 08:30
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 2705

EAB) (1725)

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:55

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 20:53
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:55

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

55 of 2705

EAB) (1725)

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:55

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 19:21
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

57 of 2705

EAB) (1725)

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:55

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 20:53
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:55

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

59 of 2705

EAB) (1725)

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:55

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 20:19
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3372005

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 11 AUG 2020 20:34

PC Open Date & Time 11 AUG 2020 12:00

PC Close Date & Time 12 AUG 2020 11:59

US3372005

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 AUG 2020 20:34
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3372005

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 17:31:13

Generated On: 09 Jun 2021 17:16:55

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3372005

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:31:13

Generated On: 09 Jun 2021 17:16:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372005

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 17:31:02

Generated On: 09 Jun 2021 17:16:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372005

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:31:02

Generated On: 09 Jun 2021 17:16:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372005

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 17:31:02

Generated On: 09 Jun 2021 17:16:55

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3372005

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:31:02

Generated On: 09 Jun 2021 17:16:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372005

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 17:31:14

Generated On: 09 Jun 2021 17:16:55

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

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 17:31:14

Generated On: 09 Jun 2021 17:16:55

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)	15 SEP 2020
Time of assessment (00:00-23:59)	13:40 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 13:40
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 17:31:14

Generated On: 09 Jun 2021 17:16:55

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	15 SEP 2020
Time of assessment (00:00-23:59)	16:05 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 16:05
Temperature (xxx.x)	35.9 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3372005

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 17:31:14

Generated On: 09 Jun 2021 17:16:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 SEP 2020

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

US3372005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 17:31:14

Generated On: 09 Jun 2021 17:16:55

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 15 SEP 2020

What was the treatment time? (00:00-23:59) 15:28 (24 HR)

Treatment Date and Time (derived) 15 SEP 2020 15:28

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

What was the frequency of the study treatment dosing? ONCE

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

US3372005

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 17:31:14

Generated On: 09 Jun 2021 17:16:55

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 SEP 2020

Collection time (00:00-23:59)

14:31 (24 HR)

Collection date and time (derived)

15 SEP 2020 14:31

US3372005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 17:31:14

Generated On: 09 Jun 2021 17:16:55

Collection date (dd MMM yyyy)			15 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:27	15 SEP 2020 14:27
Nasopharyngeal Swab 2	No		

US3372005

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:31:14

Generated On: 09 Jun 2021 17:16:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °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

15 SEP 2020 16:06

PC Open Date & Time

15 SEP 2020 15:48

PC Close Date & Time

15 SEP 2020 18:18

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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 98.5 °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 19:16
PC Open Date & Time	15 SEP 2020 19:13
PC Close Date & Time	16 SEP 2020 11:59

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

17 SEP 2020 00:44

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

17 SEP 2020 12:30

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:55

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

97.8 °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

18 SEP 2020 16:26

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 21:02

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:55

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

98.0 °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

20 SEP 2020 13:33

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 16:29

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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

15 SEP 2020 16:13

PC Open Date & Time

15 SEP 2020 15:48

PC Close Date & Time

15 SEP 2020 18:18

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 19:17

PC Open Date & Time

15 SEP 2020 19:13

PC Close Date & Time

16 SEP 2020 11:59

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:55

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

17 SEP 2020 00:45

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:55

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

17 SEP 2020 12:30

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:55

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

18 SEP 2020 16:27

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:55

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

19 SEP 2020 21:02

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:55

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

20 SEP 2020 13:33

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:55

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

21 SEP 2020 16:29

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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

No ☒

Yes ☐

PC Time stamp	15 SEP 2020 16:07
PC Open Date & Time	15 SEP 2020 15:48
PC Close Date & Time	15 SEP 2020 18:18

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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

No ☒

Yes ☐

PC Time stamp	15 SEP 2020 19:18
PC Open Date & Time	15 SEP 2020 19:13
PC Close Date & Time	16 SEP 2020 11:59

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:55

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 ☒

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:55

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 00:46
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:55

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 ☒

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:55

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 12:31
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

101 of 2705

EAB) (1725)

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:55

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 16:27
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:55

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 ☒

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:55

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 21:03
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:55

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 13:34
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:55

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

107 of 2705

EAB) (1725)

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:55

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 16:30
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3372005

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 17:31:02

Generated On: 09 Jun 2021 17:16:55

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

DATA ENTERED ON
INCORRECT VISIT. PATIENT'S
DAY 2 DELAYED

If Contact Not Made, please provide Comments

US3372005

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:31:02

Generated On: 09 Jun 2021 17:16:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372005

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 17:31:13

Generated On: 09 Jun 2021 17:16:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372005

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:31:02

Generated On: 09 Jun 2021 17:16:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372005

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 17:31:13

Generated On: 09 Jun 2021 17:16:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372005

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:31:13

Generated On: 09 Jun 2021 17:16:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372005

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 17:31:14

Generated On: 09 Jun 2021 17:16:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 17:31:14

Generated On: 09 Jun 2021 17:16:55

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) _____

US3372005

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 17:31:14

Generated On: 09 Jun 2021 17:16:55

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.

US3372005

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 17:31:14

Generated On: 09 Jun 2021 17:16:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 SEP 2020
Collection time (00:00-23:59)	11:42 (24 HR)
Collection date and time (derived)	29 SEP 2020 11:42

US3372005

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:31:14

Generated On: 09 Jun 2021 17:16:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 OCT 2020 12:01:07

Patient Cloud Open Date & Time

04 OCT 2020 00:01

Patient Cloud Close Date & Time

08 OCT 2020 23:59

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

13 OCT 2020 12:01:46

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

20 OCT 2020 15:03:49

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

01 NOV 2020 21:48:10

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 NOV 2020 22:21:24
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 22:24:02

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 NOV 2020 23:34:41

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

26 NOV 2020 22:05:29

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 12:16:17
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

10 DEC 2020 22:16:43

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

17 DEC 2020 22:01:12

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

27 DEC 2020 03:42:46

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

31 DEC 2020 23:55:39

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 JAN 2021 21:27:15
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 JAN 2021 21:43:19
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

21 JAN 2021 20:25:32

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 JAN 2021 07:00:17
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

04 FEB 2021 20:47:25

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 FEB 2021 12:27:03
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 FEB 2021 23:41:11
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

25 FEB 2021 15:32:15

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

04 MAR 2021 21:40:58

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

11 MAR 2021 15:07:38

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

18 MAR 2021 22:16:57

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 MAR 2021 21:35:49
Patient Cloud Open Date & Time	25 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

01 APR 2021 13:06:41

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

08 APR 2021 22:49:44

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

16 APR 2021 21:29:07

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

22 APR 2021 06:33:03

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

29 APR 2021 15:03:01

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUN 2021 00:01
Patient Cloud Close Date & Time	14 JUN 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 320

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

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

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

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

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

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

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUN 2021 00:01
Patient Cloud Close Date & Time	21 JUN 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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°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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 334

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

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

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

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

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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"/>

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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"/>

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	23 AUG 2021 23:59
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US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 404

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

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

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

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

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 SEP 2021 00:01
Patient Cloud Close Date & Time	13 SEP 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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="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"/>

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 SEP 2021 00:01
Patient Cloud Close Date & Time	20 SEP 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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"/>

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
Patient Cloud Close Date & Time	11 OCT 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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="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"/>

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	25 OCT 2021 23:59
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US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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"/>

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
Patient Cloud Close Date & Time	13 DEC 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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°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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 FEB 2022 00:01
Patient Cloud Close Date & Time	28 FEB 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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="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"/>

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 621

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

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

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

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

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

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

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 APR 2022 00:01
Patient Cloud Close Date & Time	18 APR 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 MAY 2022 00:01
Patient Cloud Close Date & Time	16 MAY 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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"/>

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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"/>

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUN 2022 00:01
Patient Cloud Close Date & Time	04 JUL 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2022 00:01
Patient Cloud Close Date & Time	11 JUL 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 719

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

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

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

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

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

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

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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="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"/>

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 747

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

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

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

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

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

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

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 SEP 2022 00:01
Patient Cloud Close Date & Time	12 SEP 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 SEP 2022 00:01
Patient Cloud Close Date & Time	26 SEP 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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="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"/>

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

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

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3372005

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:16:55

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 22:56:14

US3372005

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 17:31:13

Generated On: 09 Jun 2021 17:16:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372005

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:31:13

Generated On: 09 Jun 2021 17:16:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372005

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 17:31:02

Generated On: 09 Jun 2021 17:16:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372005

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:31:02

Generated On: 09 Jun 2021 17:16:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372005

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 17:31:02

Generated On: 09 Jun 2021 17:16:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372005

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:31:02

Generated On: 09 Jun 2021 17:16:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372005

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 17:31:02

Generated On: 09 Jun 2021 17:16:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372005

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:31:02

Generated On: 09 Jun 2021 17:16:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372005

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Mar 2021 16:23:25

Generated On: 09 Jun 2021 17:16:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 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

US3372005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 21:31:21

Generated On: 09 Jun 2021 17:16:55

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) _____

US3372005

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Mar 2021 16:23:25

Generated On: 09 Jun 2021 17:16:55

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.

US3372005

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Mar 2021 16:23:25

Generated On: 09 Jun 2021 17:16:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 MAR 2021
Collection time (00:00-23:59)	12:22 (24 HR)
Collection date and time (derived)	8 MAR 2021 12:22

US3372005

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Mar 2021 16:23:25

Generated On: 09 Jun 2021 17:16:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372005

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 14 Apr 2021 15:48:35

Generated On: 09 Jun 2021 17:16:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372005

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 14 Apr 2021 15:48:35

Generated On: 09 Jun 2021 17:16:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372005

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

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

US3372005

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3372005

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:16:55

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

US3372005

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:16:55

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3372005

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

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 17:31:01

Generated On: 09 Jun 2021 17:16:55

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

Visit date (dd MMM yyyy)	8 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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US3372005

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 21:31:21

Generated On: 09 Jun 2021 17:16:55

Date of updated informed consent (<i>dd MMM yyyy</i>)	8 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>)	8 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

US3372005

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 17:31:01

Generated On: 09 Jun 2021 17:16:55

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

US3372005

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 17:31:01

Generated On: 09 Jun 2021 17:16:55

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)	8 JAN 2021
Time of assessment (00:00-23:59)	12:48 (24 HR)
Vital Signs Date and Time (derived)	8 JAN 2021 12:48
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3372005

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 17:31:01

Generated On: 09 Jun 2021 17:16:55

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)	8 JAN 2021
Time of assessment (00:00-23:59)	14:25 (24 HR)
Vital Signs Date and Time (derived)	8 JAN 2021 14:25
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)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3372005

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

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 17:31:01

Generated On: 09 Jun 2021 17:16:55

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.

US3372005

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

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 17:31:01

Generated On: 09 Jun 2021 17:16:55

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 8 JAN 2021

What was the treatment time? (00:00-23:59) 13:53 (24 HR)

Treatment Date and Time (derived) 8 JAN 2021 13:53

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

US3372005

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 17:31:01

Generated On: 09 Jun 2021 17:16:55

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 JAN 2021

Collection time (00:00-23:59)

12:06 (24 HR)

Collection date and time (derived)

8 JAN 2021 12:06

US3372005

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Feb 2021 17:31:01

Generated On: 09 Jun 2021 17:16:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 JAN 2021
Collection time (00:00 - 23:59)	12:09
Collection Date and Time (derived)	8 JAN 2021 12:09

US3372005

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

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:31:01

Generated On: 09 Jun 2021 17:16:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372005

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 17:31:13

Generated On: 09 Jun 2021 17:16:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372005

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:31:13

Generated On: 09 Jun 2021 17:16:55

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

US3372005

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 17:31:01

Generated On: 09 Jun 2021 17:16:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 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

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 17:31:01

Generated On: 09 Jun 2021 17:16:55

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)	5 FEB 2021
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	5 FEB 2021 11:25
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 17:31:01

Generated On: 09 Jun 2021 17:16:55

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)	5 FEB 2021
Time of assessment (00:00-23:59)	12:35 (24 HR)
Vital Signs Date and Time (derived)	5 FEB 2021 12:35
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3372005

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 17:31:01

Generated On: 09 Jun 2021 17:16:55

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.

US3372005

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 17:31:01

Generated On: 09 Jun 2021 17:16:55

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) 5 FEB 2021

What was the treatment time? (00:00-23:59) 12:05 (24 HR)

Treatment Date and Time (derived) 5 FEB 2021 12:05

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

US3372005

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:31:01

Generated On: 09 Jun 2021 17:16:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372005

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:21:23

Generated On: 09 Jun 2021 17:16:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372005

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:31:13

Generated On: 09 Jun 2021 17:16:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372005

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Mar 2021 16:23:25

Generated On: 09 Jun 2021 17:16:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 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

US3372005

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Mar 2021 16:23:25

Generated On: 09 Jun 2021 17:16:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	8 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	12:04 (24 HR)
Vital Signs Date and Time (derived)	8 MAR 2021 12:04
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (<i>xxx</i>)	62 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	64 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3372005

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Mar 2021 16:23:25

Generated On: 09 Jun 2021 17:16:55

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.

US3372005

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Mar 2021 16:23:25

Generated On: 09 Jun 2021 17:16:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 MAR 2021
Collection time (00:00-23:59)	12:22 (24 HR)
Collection date and time (derived)	8 MAR 2021 12:22

US3372005

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 16:34:23

Generated On: 09 Jun 2021 17:16:55

AEID	USA-US056-2020-MRNA-1273-P30 1000001
Adverse event	FRACTURED LEFT HIP
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)	25 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)	26 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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	25 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	31 AUG 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 16:34:23

Generated On: 09 Jun 2021 17:16:55

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input checked="" type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
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	

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 16:34:23

Generated On: 09 Jun 2021 17:16:55

SUBJECT NOTIFIED THE SITE
OF FALLING AND FRACTURING
LEFT HIP ON THE 28-AUG-2020.
PARTIAL HIP REPLACEMENT
WAS PERFORMED ON
26-AUG-2020. SUBJECT DID NOT
NOTIFY THE SITE UNTIL
29-AUG-2020 OF THE
HOSPITALIZATION. SUBJECT
HAS BEEN TRANSFERRED TO A
REHABILITATION FACILITY ON
31-AUG-2020. MEDICAL
RECORDS HAVE BEEN
REQUESTED. SUBJECTS FIRST
INJECTION OCCURRED ON
04-AUG-2020.

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

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 16:34:23

Generated On: 09 Jun 2021 17:16:55

AEID	
Adverse event	FALL
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)	25 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)	25 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 16:34:23

Generated On: 09 Jun 2021 17:16:55

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 type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 16:34:23

Generated On: 09 Jun 2021 17:16:55

AEID	
Adverse event	INTERMITTENT CONSTIPATION
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	28 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 16:34:23

Generated On: 09 Jun 2021 17:16:55

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 16:34:23

Generated On: 09 Jun 2021 17:16:55

AEID

Adverse event

GASTROESOPHAGEAL REFLUX
DISEASE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

25 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

31 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 16:34:23

Generated On: 09 Jun 2021 17:16:55

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 22 Apr 2021 16:34:23

Generated On: 09 Jun 2021 17:16:55

AEID	
Adverse event	INSOMNIA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	28 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 22 Apr 2021 16:34:23

Generated On: 09 Jun 2021 17:16:55

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Feb 2021 17:31:01

Generated On: 09 Jun 2021 17:16:55

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

Yes ☒

No ☐

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

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

Name of Medication CENTRUM SILVER

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

	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 1990	
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 (2)

Data signed: (b) (4) 12 Feb 2021 17:31:00

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Name of Medication VITAMIN C

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Feb 2021 17:31:00

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1990
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) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

Name of Medication VITAMIN B COMPLEX

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

	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 1990
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) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

Name of Medication VITAMIN D3

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 2000

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) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

	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 1990
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) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

Name of Medication CALCIUM

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

	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 1990
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 (6)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

Name of Medication MAGNESIUM

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 420

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) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1990
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 (7)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

Name of Medication LUTEIN

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1990
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) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

Name of Medication LYCOPENE

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1990
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 (9)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

Name of Medication CO Q-10

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

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 (9)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

	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 1990
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"/>

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

Name of Medication RED YEAST RICE

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

	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 1990
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

Name of Medication PROSTATE COMPLEX

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 320

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) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

	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 1990
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 (12)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

Name of Medication KRILL OIL

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1990	
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 (13)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

Name of Medication SUPER K (VITAMIN K: VITAMIN K1, K2, MK-4 AND MK-7)

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 260

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 (13)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1990
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"/>

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

Name of Medication DHEA

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

	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 1990
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 (15)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

Name of Medication VITAMIN B-12

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1990
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"/>

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

Name of Medication TURMERIC CURCUMIN

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

	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 1990
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 (17)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

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 ☐

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

	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 NOV 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 NOV 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"/>

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

Name of Medication PNEUMONIA VACCINE

Prophylaxis Yes ☒
No ☐

Indication PNEUMONIA
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" 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 NOV 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN NOV 2019
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"/>

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

Name of Medication HERPES ZOSTER VACCINE

Prophylaxis Yes ☒
No ☐

Indication HERPES ZOSTER
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

	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 NOV 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 NOV 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"/>

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication LEFT HIP PAIN

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

	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)	28 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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

Name of Medication BISACODYL

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

	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)		28 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)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

Name of Medication ACETAMINOPHEN/OXYCODON
E

Prophylaxis Yes ☐
No ☒

Indication LEFT HIP PAIN

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

	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)		25 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)		_____
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 (23)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

Name of Medication FAMOTIDINE

Prophylaxis Yes ☒
No ☐

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

401 of 2705

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

	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)	25 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)	31 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

Name of Medication RIVAROXABAN

Prophylaxis Yes ☒
No ☐

Indication BLOOD CLOT PREVENTION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

403 of 2705

EAB) (1725)

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

	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)	28 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)	08 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

Name of Medication ZOLPIDEM

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

405 of 2705

EAB) (1725)

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 12 Feb 2021 17:31:00

Generated On: 09 Jun 2021 17:16:55

	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 SEP 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"/>

US3372005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Feb 2021 17:31:01

Generated On: 09 Jun 2021 17:16:55

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3372005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 12 Feb 2021 17:31:01

Generated On: 09 Jun 2021 17:16:55

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
26 AUG 2020	LEFT HIP HEMIARTHROPLASTY	Adverse Event	
25 AUG 2020	LEFT HIP X-RAY	Adverse Event	

US3372005

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:16:55

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

US3372005

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:16:55

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 ☐

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 19 Apr 2021 19:06:23

Generated On: 09 Jun 2021 17:16:55

SAEID	USA-US056-2020-MRNA-1273-P301000001
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)	11

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Apr 2021 19:06:23

Generated On: 09 Jun 2021 17:16:55

SAEID	USA-US056-2020-MRNA-1273-P301000001
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)	11
Date of submission (Pre-filled from custom function)	31/AUG/2020 16:13
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

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Apr 2021 19:06:23

Generated On: 09 Jun 2021 17:16:55

SAEID	USA-US056-2020-MRNA-1273-P301000001
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)	11
Date of submission (Pre-filled from custom function)	20/SEP/2020 16:14
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

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 19 Apr 2021 19:06:23

Generated On: 09 Jun 2021 17:16:55

SAEID	USA-US056-2020-MRNA-1273-P301000001
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)	11
Date of submission (Pre-filled from custom function)	12/OCT/2020 14:30
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

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 19 Apr 2021 19:06:23

Generated On: 09 Jun 2021 17:16:55

SAEID	USA-US056-2020-MRNA-1273-P301000001
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)	11
Date of submission (Pre-filled from custom function)	19/OCT/2020 15:42
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

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 19 Apr 2021 19:06:23

Generated On: 09 Jun 2021 17:16:55

SAEID	USA-US056-2020-MRNA-1273-P301000001
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)	11
Date of submission (Pre-filled from custom function)	20/OCT/2020 12:00
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

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 19 Apr 2021 19:06:23

Generated On: 09 Jun 2021 17:16:55

SAEID	USA-US056-2020-MRNA-1273-P301000001
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)	11
Date of submission (Pre-filled from custom function)	03/NOV/2020 07:59
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

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 19 Apr 2021 19:06:23

Generated On: 09 Jun 2021 17:16:55

SAEID	USA-US056-2020-MRNA-1273-P301000001
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)	11
Date of submission (Pre-filled from custom function)	19/NOV/2020 17:03
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

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Data signed: (b) (4) 19 Apr 2021 19:06:23

Generated On: 09 Jun 2021 17:16:55

SAEID	USA-US056-2020-MRNA-1273-P301000001
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)	11
Date of submission (Pre-filled from custom function)	06/JAN/2021 14:14
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

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Data signed: (b) (4) 19 Apr 2021 19:06:23

Generated On: 09 Jun 2021 17:16:55

SAEID	USA-US056-2020-MRNA-1273-P301000001
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)	11
Date of submission (Pre-filled from custom function)	01/FEB/2021 15:45
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Data signed: (b) (4) 19 Apr 2021 19:06:23

Generated On: 09 Jun 2021 17:16:55

SAEID	USA-US056-2020-MRNA-1273-P301000001
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)	11
Date of submission (Pre-filled from custom function)	18/FEB/2021 12:36
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (11)

Data signed: (b) (4) 19 Apr 2021 19:06:23

Generated On: 09 Jun 2021 17:16:55

SAEID	USA-US056-2020-MRNA-1273-P301000001
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)	11
Date of submission (Pre-filled from custom function)	19/APR/2021 06:16
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

US3372005 (Prod: Palm Beach Research Center)

US3372005

Form: Participant Creation

Generated On: 09 Jun 2021 17:16:55

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'US3372005'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 18:34:17

US3372005

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	31 Jul 2020 22:28:36

US3372005

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '31 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 18:34:18

US3372005

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Clinic (Clinic)'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:28:36

US3372005

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered 'SCRN'	System	31 Jul 2020 22:28:36

US3372005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered (b) (6) 1925'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 18:34:18

US3372005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '94'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:09

US3372005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered 'YEARS'	System	31 Jul 2020 22:29:09

US3372005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered '94'	System	31 Jul 2020 22:29:21

US3372005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Male (M)'	(b) (4) Peter Jacob (b) (4)	31 Jul 2020 22:29:09

US3372005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Peter Jacob (b) (4)	31 Jul 2020 22:29:09

US3372005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'I'	(b) (4) Peter Jacob (b) (4)	31 Jul 2020 22:29:09

US3372005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:09

US3372005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:09

US3372005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:09

US3372005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:09

US3372005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:09

US3372005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:09

US3372005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '0'	Peter Jacob (b) (4)	31 Jul 2020 22:29:09

US3372005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:55

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:09

US3372005

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:55

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '31 Jul 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:21

US3372005

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered 'Jul 2020'	System	31 Jul 2020 22:29:21

US3372005

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered '2020'	System	31 Jul 2020 22:29:21

US3372005

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:55

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Amendment 1 (1)'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:21

US3372005

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:21

US3372005

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:55

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:21

US3372005

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:55

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:21

US3372005

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:55

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	31 Jul 2020 22:29:21

US3372005

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:55

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 18:34:18

US3372005

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:55

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered 'I'	System	31 Jul 2020 22:29:33

US3372005

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:16:55

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	Peter Jacob (b) (4)	31 Jul 2020 22:29:33

US3372005

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:16:55

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	31 Jul 2020 22:29:54

US3372005

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Left inguinal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 20:50:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 20:50:09
Data point term sent to Coder	System	04 Aug 2020 20:48:57
Coding entries removed.	Peter Jacob (b) (4)	04 Aug 2020 20:48:42
User entered 'INGUINAL HERNIA - left' reason for change: Data Entry Error	(b) (4)	04 Aug 2020 20:48:42
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Inguinal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 22:32:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 22:32:18
Data point term sent to Coder	System	31 Jul 2020 22:31:05
User entered 'inguinal hernia'	Peter Jacob (b) (4)	31 Jul 2020 22:30:21

US3372005

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'un UNK 1995'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:30:21

US3372005

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:30:21

US3372005

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	31 Jul 2020 22:30:21

US3372005

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:55

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'un UNK 1995'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:30:21

US3372005

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:30:21

US3372005

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:55

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered 'Jan 1995'	System	31 Jul 2020 22:30:21

US3372005

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered '1995'	System	31 Jul 2020 22:30:21

US3372005

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered 'Jan 1995'	System	31 Jul 2020 22:30:21

US3372005

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered '1995'	System	31 Jul 2020 22:30:21

US3372005

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knee - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 22:32:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 22:32:17
Data point term sent to Coder	System	31 Jul 2020 22:31:05
User entered 'osteoarthritis left knee'	Peter Jacob (b) (4)	31 Jul 2020 22:30:44

US3372005

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'un UNK 2009'	(b) (4) Peter Jacob (b) (4)	31 Jul 2020 22:30:44

US3372005

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:30:44

US3372005

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	31 Jul 2020 22:30:44

US3372005

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:55

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'un UNK 2009'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:30:44

US3372005

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:30:44

US3372005

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:55

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered 'Jan 2009'	System	31 Jul 2020 22:30:44

US3372005

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered '2009'	System	31 Jul 2020 22:30:44

US3372005

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered 'Jan 2009'	System	31 Jul 2020 22:30:44

US3372005

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered '2009'	System	31 Jul 2020 22:30:44

US3372005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 22:32:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 22:32:17
Data point term sent to Coder	System	31 Jul 2020 22:31:05
User entered 'left knee replacement'	Peter Jacob (b) (4)	31 Jul 2020 22:31:00

US3372005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'un UNK 2009'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:31:00

US3372005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:31:00

US3372005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	31 Jul 2020 22:31:00

US3372005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:55

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'un UNK 2009'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:31:00

US3372005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:31:00

US3372005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:55

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered 'Jan 2009'	System	31 Jul 2020 22:31:00

US3372005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered '2009'	System	31 Jul 2020 22:31:00

US3372005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered 'Jan 2009'	System	31 Jul 2020 22:31:00

US3372005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered '2009'	System	31 Jul 2020 22:31:00

US3372005

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knee - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 22:33:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 22:33:18
Data point term sent to Coder	System	31 Jul 2020 22:32:06
User entered 'osteoarthritis right knee'	Peter Jacob (b) (4)	31 Jul 2020 22:31:16

US3372005

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'un UNK 2018'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:31:16

US3372005

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '0'	Peter Jacob (b) (4)	31 Jul 2020 22:31:16

US3372005

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	31 Jul 2020 22:31:16

US3372005

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:55

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'un UNK 2018'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:31:16

US3372005

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:31:16

US3372005

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:55

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered 'Jan 2018'	System	31 Jul 2020 22:31:16

US3372005

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered '2018'	System	31 Jul 2020 22:31:16

US3372005

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered 'Jan 2018'	System	31 Jul 2020 22:31:16

US3372005

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered '2018'	System	31 Jul 2020 22:31:16

US3372005

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 22:33:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 22:33:18
Data point term sent to Coder	System	31 Jul 2020 22:32:06
User entered 'right knee replacement'	Peter Jacob (b) (4)	31 Jul 2020 22:31:35

US3372005

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'un UNK 2018'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:31:35

US3372005

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:31:35

US3372005

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	31 Jul 2020 22:31:35

US3372005

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:55

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'un UNK 2018'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:31:35

US3372005

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '0'	(b) (4) Peter Jacob (b) (4)	31 Jul 2020 22:31:35

US3372005

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:55

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered 'Jan 2018'	System	31 Jul 2020 22:31:35

US3372005

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered '2018'	System	31 Jul 2020 22:31:35

US3372005

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered 'Jan 2018'	System	31 Jul 2020 22:31:35

US3372005

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered '2018'	System	31 Jul 2020 22:31:35

US3372005

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Right inguinal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 20:51:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 20:51:11
Data point term sent to Coder	System	04 Aug 2020 20:49:59
User entered 'inguinal hernia - right'	Peter Jacob (b) (4)	04 Aug 2020 20:49:36

US3372005

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'un UNK 1995'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:49:36

US3372005

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '0'	Peter Jacob (b) (4)	04 Aug 2020 20:49:36

US3372005

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:49:36

US3372005

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:55

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'un UNK 1995'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:49:36

US3372005

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '0'	Peter Jacob (b) (4)	04 Aug 2020 20:49:36

US3372005

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered 'Jan 1995'	System	04 Aug 2020 20:49:36

US3372005

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered '1995'	System	04 Aug 2020 20:49:36

US3372005

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered 'Jan 1995'	System	04 Aug 2020 20:49:36

US3372005

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered '1995'	System	04 Aug 2020 20:49:36

US3372005

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Inguinal hernia repair, LLT: Inguinal herniorrhaphy - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 20:52:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 20:52:31
Data point term sent to Coder	System	04 Aug 2020 20:51:01
User entered 'left inguinal herniorrhaphy'	Peter Jacob (b) (4)	04 Aug 2020 20:50:05

US3372005

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'un UNK 1995'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:50:05

US3372005

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:50:05

US3372005

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:50:05

US3372005

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:55

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'un UNK 1995'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:50:05

US3372005

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:50:05

US3372005

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered 'Jan 1995'	System	04 Aug 2020 20:50:05

US3372005

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered '1995'	System	04 Aug 2020 20:50:05

US3372005

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered 'Jan 1995'	System	04 Aug 2020 20:50:05

US3372005

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered '1995'	System	04 Aug 2020 20:50:05

US3372005

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Inguinal hernia repair, LLT: Inguinal herniorrhaphy - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 20:52:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 20:52:02
Data point term sent to Coder	System	04 Aug 2020 20:51:01
User entered 'right inguinal herniorrhaphy'	Peter Jacob (b) (4)	04 Aug 2020 20:50:20
	(b) (4)	

US3372005

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'un UNK 1995'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:50:20

US3372005

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:50:20

US3372005

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:50:20

US3372005

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:55

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'un UNK 1995'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:50:20

US3372005

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:50:20

US3372005

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered 'Jan 1995'	System	04 Aug 2020 20:50:20

US3372005

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered '1995'	System	04 Aug 2020 20:50:20

US3372005

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered 'Jan 1995'	System	04 Aug 2020 20:50:20

US3372005

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered '1995'	System	04 Aug 2020 20:50:20

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '31 Jul 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '14:52'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered '31 Jul 2020 14:52'	System	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '162.6' cm	(b) (4) Peter Jacob (b) (4)	31 Jul 2020 22:32:30
DataPoint set to visible.	(b) (4) System	31 Jul 2020 22:29:33

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
Signature has been broken.	(b) (4) Mary Sergalis (b) (4)	09 Mar 2021 14:11:09
User entered '60.4' kg reason for change: Data Entry Error	Mary Sergalis (b) (4)	09 Mar 2021 14:11:09
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '133.2' kg	(b) (4) Peter Jacob (b) (4)	31 Jul 2020 22:32:30
DataPoint set to visible.	(b) (4) System	31 Jul 2020 22:29:33

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered '22.84525'	System	09 Mar 2021 14:11:09
Amendment Manager: User entered '50.38058'	System	16 Sep 2020 23:39:54
User entered '50.4'	System	31 Jul 2020 22:32:30
DataPoint set to visible.	System	31 Jul 2020 22:29:33

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered 'kg/m2'	System	31 Jul 2020 22:32:30
DataPoint set to visible.	System	31 Jul 2020 22:29:33

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '36.1' C	(b) (4) Peter Jacob (b) (4)	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) Peter Jacob (b) (4)	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '58'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered 'bpm'	System	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '14'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered 'breaths/min'	System	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '126'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered 'mmHg'	System	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '67'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User entered 'mmHg'	System	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57

US3372005

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	31 Jul 2020 22:32:36

US3372005

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.	(b) (4)	30 Sep 2020 21:09:13
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		15 Sep 2020 19:09:39
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	27 Aug 2020 13:04:03
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		04 Aug 2020 16:50:54
User entered '31 Jul 2020'	Peter Jacob (b) (4)	31 Jul 2020 22:32:36
	(b) (4)	

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

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)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

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)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

[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)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

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)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'No (N)'	Peter Jacob (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

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)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

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)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

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)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

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)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'No (N)'	Peter Jacob (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '94 years old'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'I'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '0'	(b) (4) Peter Jacob (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

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)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '0'	Peter Jacob (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

[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)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

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)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '0'	Peter Jacob (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '0'	(b) (4) Peter Jacob (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:33:57
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	04 Aug 2020 16:50:54

US3372005

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '04 Aug 2020' reason for change: Data Entry Error	(b) (4) Mary Sergalis (b) (4)	10 Nov 2020 17:40:32
User entered '4 Aug 2020'	Kimarie Lee-Russell (b) (4)	04 Aug 2020 16:50:54

US3372005

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Clinic (Clinic)'	(b) (4) Kimarie Lee-Russell (b) (4)	04 Aug 2020 16:50:54

US3372005

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User entered 'VISIT1'	System	04 Aug 2020 16:50:54

US3372005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered '04 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 16:49:39

US3372005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:55

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 01:32:18
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:32:18
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Aug 2020 16:49:39
User entered '184643' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 16:49:39

US3372005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:55

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 16:49:39

US3372005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:55

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)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	04 Aug 2020 16:51:23

US3372005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:55

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)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	04 Aug 2020 16:51:23

US3372005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User closed query 'Per CDM: per sponsor review, BMI ≥ 40 kg/m2 yet participant is not recorded as at risk. Please reconcile' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 12:01:35
Query 'Per CDM: per sponsor review, BMI ≥ 40 kg/m2 yet participant is not recorded as at risk. Please reconcile' answered with 'Weight was corrected to reflect kg=60.4 which puts their BMI at 22.9 so this is not a risk' (Site from DM).	Mary Sergalis (b) (4)	09 Mar 2021 14:13:38
User opened query 'Per CDM: per sponsor review, BMI ≥ 40 kg/m2 yet participant is not recorded as at risk. Please reconcile' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 21:09:45
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	04 Aug 2020 16:51:23

US3372005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:55

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	04 Aug 2020 16:51:23

US3372005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:55

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	04 Aug 2020 16:51:23

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '162.6' cm	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '61.2' kg	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '162.6' cm	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '61.2' kg	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '04 Aug 2020'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '12:25'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User entered '04 Aug 2020 12:25'	System	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '36.6' C	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '66'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User entered 'bpm'	System	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '18'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User entered 'breaths/min'	System	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '126'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User entered 'mmHg'	System	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '74'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User entered 'mmHg'	System	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '162.6' cm	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '61.2' kg	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:53:12

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:53:12

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '04 Aug 2020'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:53:12

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
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)	10 Aug 2020 11:26:18
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 completed at least 30 minutes after dose time' (Site from System).	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:53:38
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).		04 Aug 2020 20:53:12
User entered '13:50'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:53:12

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User entered '04 Aug 2020 13:50'	System	04 Aug 2020 20:53:12

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '36.1' C	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:53:12

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:53:12

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:53:12

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '56'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:53:12

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User entered 'bpm'	System	04 Aug 2020 20:53:12

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '18'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:53:12

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User entered 'breaths/min'	System	04 Aug 2020 20:53:12

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '122'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:53:12

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User entered 'mmHg'	System	04 Aug 2020 20:53:12

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '70'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:53:12

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User entered 'mmHg'	System	04 Aug 2020 20:53:12

US3372005

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:53:48

US3372005

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '04 Aug 2020'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:53:48

US3372005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	04 Aug 2020 17:35:41

US3372005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	04 Aug 2020 17:35:41

US3372005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

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)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	04 Aug 2020 17:35:41

US3372005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User entered 'MRNA-1273 OR PLACEBO'	System	04 Aug 2020 17:35:41

US3372005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '4 Aug 2020'	(b) (4) Kimarie Lee-Russell (b) (4)	04 Aug 2020 17:35:41

US3372005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '13:20'	(b) (4) Kimarie Lee-Russell (b) (4)	04 Aug 2020 17:35:41

US3372005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User entered '4 Aug 2020 13:20'	System	04 Aug 2020 17:35:41

US3372005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Kimarie Lee-Russell (b) (4)	04 Aug 2020 17:35:41

US3372005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User entered 'ONCE'	System	04 Aug 2020 17:35:41

US3372005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User entered 'INTRAMUSCULAR'	System	04 Aug 2020 17:35:41

US3372005

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	04 Aug 2020 17:36:31

US3372005

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '04 Aug 2020' reason for change: Data Entry Error	(b) (4) Mary Sergalis (b) (4)	10 Nov 2020 17:40:42
User entered '4 Aug 2020'	Kimarie Lee-Russell (b) (4)	04 Aug 2020 17:36:31

US3372005

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '12:45'	(b) (4) Kimarie Lee-Russell (b) (4)	04 Aug 2020 17:36:31

US3372005

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User entered '04 Aug 2020 12:45'	System	10 Nov 2020 17:40:42
User entered '4 Aug 2020 12:45'	System	04 Aug 2020 17:36:31

US3372005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:16:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '04 Aug 2020'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:54:18

US3372005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:54:18

US3372005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:54:18

US3372005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:55

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '12:42'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:54:18

US3372005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:55

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User entered '04 Aug 2020 12:42'	System	04 Aug 2020 20:54:18

US3372005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:54:18

US3372005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:54:18

US3372005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:54:18

US3372005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User entered empty.	System	04 Aug 2020 20:54:18

US3372005

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:55:15

US3372005

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User entered 'I'	System	04 Aug 2020 20:55:15

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-04T14:06:25', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'bb958850-7fe8-4025-8c52-d409a202bf5d' User entered 'Yes (Y)'	System	04 Aug 2020 18:07:01
	System	04 Aug 2020 18:07:01

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-04T14:06:41', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'bb958850-7fe8-4025-8c52-d409a202bf5d' User entered '97.0'	System	04 Aug 2020 18:07:01
	System	04 Aug 2020 18:07:01

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-04T14:06:47', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'bb958850-7fe8-4025-8c52-d409a202bf5d'	System	04 Aug 2020 18:07:01
User entered 'No (N)'	System	04 Aug 2020 18:07:01

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-04T14:06:55', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'bb958850-7fe8-4025-8c52-d409a202bf5d' User entered '04 Aug 2020 14:06'	System	04 Aug 2020 18:07:01
	System	04 Aug 2020 18:07:01

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '04 Aug 2020 13:40'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '04 Aug 2020 16:10'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-05T08:43:26', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '6d1d5639-e2af-4ad9-a4b3-e8d5bdc49f7b' User entered 'Yes (Y)'	System	05 Aug 2020 12:43:54
	System	05 Aug 2020 12:43:54

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-05T08:43:35', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '6d1d5639-e2af-4ad9-a4b3-e8d5bdc49f7b' User entered '97.8'	System	05 Aug 2020 12:43:54
	System	05 Aug 2020 12:43:54

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-05T08:43:39', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '6d1d5639-e2af-4ad9-a4b3-e8d5bdc49f7b'	System	05 Aug 2020 12:43:54
User entered 'No (N)'	System	05 Aug 2020 12:43:54

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-05T08:43:52', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '6d1d5639-e2af-4ad9-a4b3-e8d5bdc49f7b' User entered '05 Aug 2020 08:43'	System	05 Aug 2020 12:43:54
	System	05 Aug 2020 12:43:54

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '04 Aug 2020 17:05'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 2'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-06T09:25:40', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '362d0482-6af1-4338-84de-af548a29bb01' User entered 'Yes (Y)'	System	06 Aug 2020 13:26:05
	System	06 Aug 2020 13:26:05

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-06T09:25:49', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '362d0482-6af1-4338-84de-af548a29bb01' User entered '97.5'	System	06 Aug 2020 13:26:05
	System	06 Aug 2020 13:26:05

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-06T09:25:54', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '362d0482-6af1-4338-84de-af548a29bb01'	System	06 Aug 2020 13:26:05
User entered 'No (N)'	System	06 Aug 2020 13:26:05

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-06T09:26:04', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '362d0482-6af1-4338-84de-af548a29bb01' User entered '06 Aug 2020 09:26'	System	06 Aug 2020 13:26:05
	System	06 Aug 2020 13:26:05

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 3'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:55

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T08:28:29', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '88b3750f-c380-464b-bc70-9bd96c02aeca' User entered 'Yes (Y)'	System	07 Aug 2020 12:28:53
	System	07 Aug 2020 12:28:53

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T08:28:36', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '88b3750f-c380-464b-bc70-9bd96c02aeca' User entered '97.5'	System	07 Aug 2020 12:28:53
	System	07 Aug 2020 12:28:53

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T08:28:44', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '88b3750f-c380-464b-bc70-9bd96c02aeca'	System	07 Aug 2020 12:28:53
User entered 'No (N)'	System	07 Aug 2020 12:28:53

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T08:28:52', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '88b3750f-c380-464b-bc70-9bd96c02aeca'	System	07 Aug 2020 12:28:53
User entered '07 Aug 2020 08:28'	System	07 Aug 2020 12:28:53

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 4'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T20:51:21', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '0d276d40-aa61-4fde-b7f9-161eb2316bd1' User entered 'Yes (Y)'	System	08 Aug 2020 00:51:41
	System	08 Aug 2020 00:51:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T20:51:29', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '0d276d40-aa61-4fde-b7f9-161eb2316bd1' User entered '97.8'	System	08 Aug 2020 00:51:41
	System	08 Aug 2020 00:51:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T20:51:33', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '0d276d40-aa61-4fde-b7f9-161eb2316bd1' User entered 'No (N)'	System	08 Aug 2020 00:51:41
	System	08 Aug 2020 00:51:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T20:51:40', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '0d276d40-aa61-4fde-b7f9-161eb2316bd1' User entered '07 Aug 2020 20:51'	System	08 Aug 2020 00:51:41
	System	08 Aug 2020 00:51:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 5'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-08T19:19:45', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '9a3957e9-ef9e-4336-8c33-ea97455761a6' User entered 'Yes (Y)'	System	08 Aug 2020 23:20:04
	System	08 Aug 2020 23:20:04

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-08T19:19:52', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '9a3957e9-ef9e-4336-8c33-ea97455761a6' User entered '97.8'	System	08 Aug 2020 23:20:04
	System	08 Aug 2020 23:20:04

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-08T19:19:56', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '9a3957e9-ef9e-4336-8c33-ea97455761a6'	System	08 Aug 2020 23:20:04
User entered 'No (N)'	System	08 Aug 2020 23:20:04

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-08T19:20:03', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '9a3957e9-ef9e-4336-8c33-ea97455761a6'	System	08 Aug 2020 23:20:04
User entered '08 Aug 2020 19:20'	System	08 Aug 2020 23:20:04

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 6'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-09T20:51:28', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '0a771fe8-3646-4549-bf93-7e9481334368' User entered 'Yes (Y)'	System	10 Aug 2020 00:51:53
	System	10 Aug 2020 00:51:53

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-09T20:51:36', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '0a771fe8-3646-4549-bf93-7e9481334368' User entered '97.8'	System	10 Aug 2020 00:51:53
	System	10 Aug 2020 00:51:53

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-09T20:51:42', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '0a771fe8-3646-4549-bf93-7e9481334368' User entered 'No (N)'	System	10 Aug 2020 00:51:53
	System	10 Aug 2020 00:51:53

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-09T20:51:48', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '0a771fe8-3646-4549-bf93-7e9481334368' User entered '09 Aug 2020 20:51'	System	10 Aug 2020 00:51:53
	System	10 Aug 2020 00:51:53

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 7'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-10T20:17:58', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'e132a0b5-ca36-4f9f-8599-6db0941478c8' User entered 'Yes (Y)'	System	11 Aug 2020 00:18:28
	System	11 Aug 2020 00:18:28

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-10T20:18:05', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'e132a0b5-ca36-4f9f-8599-6db0941478c8' User entered '98.0'	System	11 Aug 2020 00:18:28
	System	11 Aug 2020 00:18:28

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-10T20:18:11', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'e132a0b5-ca36-4f9f-8599-6db0941478c8'	System	11 Aug 2020 00:18:28
User entered 'No (N)'	System	11 Aug 2020 00:18:28

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-10T20:18:25', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'e132a0b5-ca36-4f9f-8599-6db0941478c8' User entered '10 Aug 2020 20:18'	System	11 Aug 2020 00:18:28
	System	11 Aug 2020 00:18:28

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-04T14:07:14', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '113d1baa-c421-429d-92ce-5122cc81ca24'	System	04 Aug 2020 18:07:37
User entered 'None (1)'	System	04 Aug 2020 18:07:37

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-04T14:07:22', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '113d1baa-c421-429d-92ce-5122cc81ca24' User entered 'No (N)'	System	04 Aug 2020 18:07:37
	System	04 Aug 2020 18:07:37

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-04T14:07:27', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '113d1baa-c421-429d-92ce-5122cc81ca24' User entered 'No (N)'	System	04 Aug 2020 18:07:37
	System	04 Aug 2020 18:07:37

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-04T14:07:32', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '113d1baa-c421-429d-92ce-5122cc81ca24'	System	04 Aug 2020 18:07:37
User entered 'None (1)'	System	04 Aug 2020 18:07:37

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-04T14:07:35', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '113d1baa-c421-429d-92ce-5122cc81ca24' User entered '04 Aug 2020 14:07'	System	04 Aug 2020 18:07:37
	System	04 Aug 2020 18:07:37

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '04 Aug 2020 13:40'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '04 Aug 2020 16:10'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-05T08:44:09', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'c99e3dac-bb28-4238-8c80-a30b2f80b264'	System	05 Aug 2020 12:44:36
User entered 'None (1)'	System	05 Aug 2020 12:44:36

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-05T08:44:13', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'c99e3dac-bb28-4238-8c80-a30b2f80b264'	System	05 Aug 2020 12:44:36
User entered 'No (N)'	System	05 Aug 2020 12:44:36

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-05T08:44:20', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'c99e3dac-bb28-4238-8c80-a30b2f80b264'	System	05 Aug 2020 12:44:36
User entered 'No (N)'	System	05 Aug 2020 12:44:36

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-05T08:44:27', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'c99e3dac-bb28-4238-8c80-a30b2f80b264'	System	05 Aug 2020 12:44:36
User entered 'None (1)'	System	05 Aug 2020 12:44:36

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-05T08:44:31', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'c99e3dac-bb28-4238-8c80-a30b2f80b264' User entered '05 Aug 2020 08:44'	System	05 Aug 2020 12:44:36
	System	05 Aug 2020 12:44:36

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '04 Aug 2020 17:05'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 2'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-06T09:26:12', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'f25b61e3-c8fb-4d5e-b294-afccaa4d9a1f' User entered 'None (1)'	System	06 Aug 2020 13:26:38
	System	06 Aug 2020 13:26:38

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-06T09:26:16', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'f25b61e3-c8fb-4d5e-b294-afccaa4d9a1f' User entered 'No (N)'	System	06 Aug 2020 13:26:38
	System	06 Aug 2020 13:26:38

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-06T09:26:21', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'f25b61e3-c8fb-4d5e-b294-afccaa4d9a1f' User entered 'No (N)'	System	06 Aug 2020 13:26:38
	System	06 Aug 2020 13:26:38

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-06T09:26:28', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'f25b61e3-c8fb-4d5e-b294-afccaa4d9a1f' User entered 'None (1)'	System	06 Aug 2020 13:26:38
	System	06 Aug 2020 13:26:38

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-06T09:26:35', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'f25b61e3-c8fb-4d5e-b294-afccaa4d9a1f' User entered '06 Aug 2020 09:26'	System	06 Aug 2020 13:26:38
	System	06 Aug 2020 13:26:38

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 3'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T08:29:01', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '87a6cf9e-c2ee-4956-911c-a8b30fe4b330'	System	07 Aug 2020 12:29:30
User entered 'None (1)'	System	07 Aug 2020 12:29:30

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T08:29:05', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '87a6cf9e-c2ee-4956-911c-a8b30fe4b330'	System	07 Aug 2020 12:29:30
User entered 'No (N)'	System	07 Aug 2020 12:29:30

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T08:29:11', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '87a6cf9e-c2ee-4956-911c-a8b30fe4b330'	System	07 Aug 2020 12:29:30
User entered 'No (N)'	System	07 Aug 2020 12:29:30

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T08:29:18', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '87a6cf9e-c2ee-4956-911c-a8b30fe4b330'	System	07 Aug 2020 12:29:30
User entered 'None (1)'	System	07 Aug 2020 12:29:30

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T08:29:29', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '87a6cf9e-c2ee-4956-911c-a8b30fe4b330'	System	07 Aug 2020 12:29:30
User entered '07 Aug 2020 08:29'	System	07 Aug 2020 12:29:30

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 4'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T20:51:47', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '9e9b8884-245a-4a64-b843-759b02ea3de5'	System	08 Aug 2020 00:52:14
User entered 'None (1)'	System	08 Aug 2020 00:52:14

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T20:51:52', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '9e9b8884-245a-4a64-b843-759b02ea3de5'	System	08 Aug 2020 00:52:14
User entered 'No (N)'	System	08 Aug 2020 00:52:14

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T20:52:02', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '9e9b8884-245a-4a64-b843-759b02ea3de5'	System	08 Aug 2020 00:52:14
User entered 'No (N)'	System	08 Aug 2020 00:52:14

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T20:52:07', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '9e9b8884-245a-4a64-b843-759b02ea3de5'	System	08 Aug 2020 00:52:14
User entered 'None (1)'	System	08 Aug 2020 00:52:14

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T20:52:11', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '9e9b8884-245a-4a64-b843-759b02ea3de5'	System	08 Aug 2020 00:52:14
User entered '07 Aug 2020 20:52'	System	08 Aug 2020 00:52:14

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 5'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-08T19:20:10', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2b4a3af4-0428-4ed2-a828-c59986e80db7'	System	08 Aug 2020 23:20:35
User entered 'None (1)'	System	08 Aug 2020 23:20:35

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-08T19:20:14', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2b4a3af4-0428-4ed2-a828-c59986e80db7'	System	08 Aug 2020 23:20:35
User entered 'No (N)'	System	08 Aug 2020 23:20:35

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-08T19:20:18', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2b4a3af4-0428-4ed2-a828-c59986e80db7'	System	08 Aug 2020 23:20:35
User entered 'No (N)'	System	08 Aug 2020 23:20:35

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-08T19:20:25', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2b4a3af4-0428-4ed2-a828-c59986e80db7' User entered 'None (1)'	System	08 Aug 2020 23:20:35
	System	08 Aug 2020 23:20:35

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-08T19:20:34', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2b4a3af4-0428-4ed2-a828-c59986e80db7'	System	08 Aug 2020 23:20:35
User entered '08 Aug 2020 19:20'	System	08 Aug 2020 23:20:35

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 6'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-09T20:51:54', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'ceecedca-c62d-49df-b3f0-a16bee589bc5'	System	10 Aug 2020 00:52:26
User entered 'None (1)'	System	10 Aug 2020 00:52:26

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-09T20:51:58', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'ceecedca-c62d-49df-b3f0-a16bee589bc5'	System	10 Aug 2020 00:52:26
User entered 'No (N)'	System	10 Aug 2020 00:52:26

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-09T20:52:02', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'ceecedca-c62d-49df-b3f0-a16bee589bc5'	System	10 Aug 2020 00:52:26
User entered 'No (N)'	System	10 Aug 2020 00:52:26

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-09T20:52:11', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'ceecedca-c62d-49df-b3f0-a16bee589bc5'	System	10 Aug 2020 00:52:26
User entered 'None (1)'	System	10 Aug 2020 00:52:26

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-09T20:52:21', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'ceecedca-c62d-49df-b3f0-a16bee589bc5' User entered '09 Aug 2020 20:52'	System	10 Aug 2020 00:52:26
	System	10 Aug 2020 00:52:26

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 7'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-10T20:18:32', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '0fbf41c8-497d-4b89-acc9-eb690c018f9b'	System	11 Aug 2020 00:18:57
User entered 'None (1)'	System	11 Aug 2020 00:18:57

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-10T20:18:36', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '0fbf41c8-497d-4b89-acc9-eb690c018f9b'	System	11 Aug 2020 00:18:57
User entered 'No (N)'	System	11 Aug 2020 00:18:57

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-10T20:18:40', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '0fbf41c8-497d-4b89-acc9-eb690c018f9b' User entered 'No (N)'	System	11 Aug 2020 00:18:57
	System	11 Aug 2020 00:18:57

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-10T20:18:44', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '0fbf41c8-497d-4b89-acc9-eb690c018f9b'	System	11 Aug 2020 00:18:57
User entered 'None (1)'	System	11 Aug 2020 00:18:57

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-10T20:18:53', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '0fbf41c8-497d-4b89-acc9-eb690c018f9b' User entered '10 Aug 2020 20:18'	System	11 Aug 2020 00:18:57
	System	11 Aug 2020 00:18:57

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-04T14:07:45', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '33835c0d-bd78-44cc-8805-83a56683aedef' User entered 'None (0)'	System	04 Aug 2020 18:08:24
	System	04 Aug 2020 18:08:24

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-04T14:07:51', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '33835c0d-bd78-44cc-8805-83a56683aedef' User entered 'None (0)'	System	04 Aug 2020 18:08:24
	System	04 Aug 2020 18:08:24

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-04T14:07:56', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '33835c0d-bd78-44cc-8805-83a56683aedef' User entered 'None (0)'	System	04 Aug 2020 18:08:24
	System	04 Aug 2020 18:08:24

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-04T14:08:01', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '33835c0d-bd78-44cc-8805-83a56683aedef' User entered 'None (0)'	System	04 Aug 2020 18:08:24
	System	04 Aug 2020 18:08:24

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-04T14:08:05', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '33835c0d-bd78-44cc-8805-83a56683aedef' User entered 'None (0)'	System	04 Aug 2020 18:08:24
	System	04 Aug 2020 18:08:24

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-04T14:08:09', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '33835c0d-bd78-44cc-8805-83a56683aedef' User entered 'None (0)'	System	04 Aug 2020 18:08:24
	System	04 Aug 2020 18:08:24

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-04T14:08:16', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '33835c0d-bd78-44cc-8805-83a56683aedef' User entered 'No (N)'	System	04 Aug 2020 18:08:24
	System	04 Aug 2020 18:08:24

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-04T14:08:22', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '33835c0d-bd78-44cc-8805-83a56683aedef' User entered '04 Aug 2020 14:08'	System	04 Aug 2020 18:08:24
	System	04 Aug 2020 18:08:24

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '04 Aug 2020 13:40'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '04 Aug 2020 16:10'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-05T08:44:39', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '911a4dfa-a9ca-4014-8ed7-b345df8bf3fd' User entered 'None (0)'	System	05 Aug 2020 12:45:16
	System	05 Aug 2020 12:45:16

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-05T08:44:42', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '911a4dfa-a9ca-4014-8ed7-b345df8bf3fd' User entered 'None (0)'	System	05 Aug 2020 12:45:16
	System	05 Aug 2020 12:45:16

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-05T08:44:44', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '911a4dfa-a9ca-4014-8ed7-b345df8bf3fd' User entered 'None (0)'	System	05 Aug 2020 12:45:16
	System	05 Aug 2020 12:45:16

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-05T08:44:47', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '911a4dfa-a9ca-4014-8ed7-b345df8bf3fd' User entered 'None (0)'	System	05 Aug 2020 12:45:16
	System	05 Aug 2020 12:45:16

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-05T08:44:51', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '911a4dfa-a9ca-4014-8ed7-b345df8bf3fd' User entered 'None (0)'	System	05 Aug 2020 12:45:16
	System	05 Aug 2020 12:45:16

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-05T08:44:56', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '911a4dfa-a9ca-4014-8ed7-b345df8bf3fd' User entered 'None (0)'	System	05 Aug 2020 12:45:16
	System	05 Aug 2020 12:45:16

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-05T08:45:08', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '911a4dfa-a9ca-4014-8ed7-b345df8bf3fd'	System	05 Aug 2020 12:45:16
User entered 'No (N)'	System	05 Aug 2020 12:45:16

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-05T08:45:14', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '911a4dfa-a9ca-4014-8ed7-b345df8bf3fd' User entered '05 Aug 2020 08:45'	System	05 Aug 2020 12:45:16
	System	05 Aug 2020 12:45:16

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '04 Aug 2020 17:05'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 2'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-06T09:26:46', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '43f71d65-b15c-4601-9d7f-c80bf4e29004'	System	06 Aug 2020 13:27:23
User entered 'None (0)'	System	06 Aug 2020 13:27:23

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-06T09:26:51', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '43f71d65-b15c-4601-9d7f-c80bf4e29004'	System	06 Aug 2020 13:27:23
User entered 'None (0)'	System	06 Aug 2020 13:27:23

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-06T09:26:56', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '43f71d65-b15c-4601-9d7f-c80bf4e29004'	System	06 Aug 2020 13:27:23
User entered 'None (0)'	System	06 Aug 2020 13:27:23

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-06T09:27:00', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '43f71d65-b15c-4601-9d7f-c80bf4e29004' User entered 'None (0)'	System	06 Aug 2020 13:27:23
	System	06 Aug 2020 13:27:23

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-06T09:27:04', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '43f71d65-b15c-4601-9d7f-c80bf4e29004' User entered 'None (0)'	System	06 Aug 2020 13:27:23
	System	06 Aug 2020 13:27:23

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-06T09:27:10', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '43f71d65-b15c-4601-9d7f-c80bf4e29004'	System	06 Aug 2020 13:27:23
User entered 'None (0)'	System	06 Aug 2020 13:27:23

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-06T09:27:15', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '43f71d65-b15c-4601-9d7f-c80bf4e29004'	System	06 Aug 2020 13:27:23
User entered 'No (N)'	System	06 Aug 2020 13:27:23

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-06T09:27:21', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '43f71d65-b15c-4601-9d7f-c80bf4e29004' User entered '06 Aug 2020 09:27'	System	06 Aug 2020 13:27:23
	System	06 Aug 2020 13:27:23

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 3'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T08:29:41', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '664bb8dc-81fe-43a2-8d5d-fa0433a157c2' User entered 'None (0)'	System	07 Aug 2020 12:30:30
	System	07 Aug 2020 12:30:30

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T08:29:46', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '664bb8dc-81fe-43a2-8d5d-fa0433a157c2' User entered 'None (0)'	System	07 Aug 2020 12:30:30
	System	07 Aug 2020 12:30:30

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T08:29:49', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '664bb8dc-81fe-43a2-8d5d-fa0433a157c2' User entered 'None (0)'	System	07 Aug 2020 12:30:30
	System	07 Aug 2020 12:30:30

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T08:29:53', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '664bb8dc-81fe-43a2-8d5d-fa0433a157c2' User entered 'None (0)'	System	07 Aug 2020 12:30:30
	System	07 Aug 2020 12:30:30

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T08:29:57', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '664bb8dc-81fe-43a2-8d5d-fa0433a157c2' User entered 'None (0)'	System	07 Aug 2020 12:30:30
	System	07 Aug 2020 12:30:30

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T08:30:01', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '664bb8dc-81fe-43a2-8d5d-fa0433a157c2' User entered 'None (0)'	System	07 Aug 2020 12:30:30
	System	07 Aug 2020 12:30:30

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T08:30:07', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '664bb8dc-81fe-43a2-8d5d-fa0433a157c2'	System	07 Aug 2020 12:30:30
User entered 'No (N)'	System	07 Aug 2020 12:30:30

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T08:30:28', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '664bb8dc-81fe-43a2-8d5d-fa0433a157c2'	System	07 Aug 2020 12:30:30
User entered '07 Aug 2020 08:30'	System	07 Aug 2020 12:30:30

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 4'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T20:52:21', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '6b73b94e-24c1-4b63-9472-ed0d3119c083' User entered 'None (0)'	System	08 Aug 2020 00:53:06
	System	08 Aug 2020 00:53:06

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T20:52:24', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '6b73b94e-24c1-4b63-9472-ed0d3119c083' User entered 'None (0)'	System	08 Aug 2020 00:53:06
	System	08 Aug 2020 00:53:06

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T20:52:28', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '6b73b94e-24c1-4b63-9472-ed0d3119c083' User entered 'None (0)'	System	08 Aug 2020 00:53:06
	System	08 Aug 2020 00:53:06

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T20:52:42', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '6b73b94e-24c1-4b63-9472-ed0d3119c083'	System	08 Aug 2020 00:53:06
User entered 'No interference with activity (1)'	System	08 Aug 2020 00:53:06

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T20:52:50', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '6b73b94e-24c1-4b63-9472-ed0d3119c083' User entered 'None (0)'	System	08 Aug 2020 00:53:06
	System	08 Aug 2020 00:53:06

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T20:52:53', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '6b73b94e-24c1-4b63-9472-ed0d3119c083' User entered 'None (0)'	System	08 Aug 2020 00:53:06
	System	08 Aug 2020 00:53:06

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T20:52:57', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '6b73b94e-24c1-4b63-9472-ed0d3119c083'	System	08 Aug 2020 00:53:06
User entered 'No (N)'	System	08 Aug 2020 00:53:06

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-07T20:53:04', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '6b73b94e-24c1-4b63-9472-ed0d3119c083' User entered '07 Aug 2020 20:53'	System	08 Aug 2020 00:53:06
	System	08 Aug 2020 00:53:06

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 5'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-08T19:20:43', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'be50a5cc-ce8d-49af-b631-cfc97f4ffbe3'	System	08 Aug 2020 23:21:33
User entered 'None (0)'	System	08 Aug 2020 23:21:33

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-08T19:20:47', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'be50a5cc-ce8d-49af-b631-cfc97f4ffbe3'	System	08 Aug 2020 23:21:33
User entered 'None (0)'	System	08 Aug 2020 23:21:33

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-08T19:20:50', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'be50a5cc-ce8d-49af-b631-cfc97f4ffbe3'	System	08 Aug 2020 23:21:33
User entered 'None (0)'	System	08 Aug 2020 23:21:33

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-08T19:20:59', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'be50a5cc-ce8d-49af-b631-cfc97f4ffbe3'	System	08 Aug 2020 23:21:33
User entered 'No interference with activity (1)'	System	08 Aug 2020 23:21:33

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-08T19:21:03', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'be50a5cc-ce8d-49af-b631-cfc97f4ffbe3'	System	08 Aug 2020 23:21:33
User entered 'None (0)'	System	08 Aug 2020 23:21:33

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-08T19:21:07', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'be50a5cc-ce8d-49af-b631-cfc97f4ffbe3'	System	08 Aug 2020 23:21:33
User entered 'None (0)'	System	08 Aug 2020 23:21:33

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-08T19:21:11', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'be50a5cc-ce8d-49af-b631-cfc97f4ffbe3'	System	08 Aug 2020 23:21:33
User entered 'No (N)'	System	08 Aug 2020 23:21:33

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-08T19:21:32', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'be50a5cc-ce8d-49af-b631-cfc97f4ffbe3'	System	08 Aug 2020 23:21:33
User entered '08 Aug 2020 19:21'	System	08 Aug 2020 23:21:33

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 6'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-09T20:52:28', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'bb2ef5f5-8c97-4540-b3eb-70eded2c11ea' User entered 'None (0)'	System	10 Aug 2020 00:53:23
	System	10 Aug 2020 00:53:23

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-09T20:52:32', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'bb2ef5f5-8c97-4540-b3eb-70eded2c11ea' User entered 'None (0)'	System	10 Aug 2020 00:53:23
	System	10 Aug 2020 00:53:23

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-09T20:52:36', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'bb2ef5f5-8c97-4540-b3eb-70eded2c11ea' User entered 'None (0)'	System	10 Aug 2020 00:53:23
	System	10 Aug 2020 00:53:23

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-09T20:52:43', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'bb2ef5f5-8c97-4540-b3eb-70eded2c11ea'	System	10 Aug 2020 00:53:23
User entered 'No interference with activity (1)'	System	10 Aug 2020 00:53:23

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-09T20:52:47', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'bb2ef5f5-8c97-4540-b3eb-70eded2c11ea' User entered 'None (0)'	System	10 Aug 2020 00:53:23
	System	10 Aug 2020 00:53:23

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-09T20:52:52', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'bb2ef5f5-8c97-4540-b3eb-70eded2c11ea' User entered 'None (0)'	System	10 Aug 2020 00:53:23
	System	10 Aug 2020 00:53:23

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-09T20:52:59', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'bb2ef5f5-8c97-4540-b3eb-70eded2c11ea' User entered 'No (N)'	System	10 Aug 2020 00:53:23
	System	10 Aug 2020 00:53:23

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-09T20:53:21', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'bb2ef5f5-8c97-4540-b3eb-70eded2c11ea'	System	10 Aug 2020 00:53:23
User entered '09 Aug 2020 20:53'	System	10 Aug 2020 00:53:23

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 7'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-10T20:18:59', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'c5010197-8b24-4054-b04a-77fad547fe47'	System	11 Aug 2020 00:19:37
User entered 'None (0)'	System	11 Aug 2020 00:19:37

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-10T20:19:04', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'c5010197-8b24-4054-b04a-77fad547fe47'	System	11 Aug 2020 00:19:37
User entered 'None (0)'	System	11 Aug 2020 00:19:37

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-10T20:19:08', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'c5010197-8b24-4054-b04a-77fad547fe47' User entered 'None (0)'	System	11 Aug 2020 00:19:37
	System	11 Aug 2020 00:19:37

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-10T20:19:13', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'c5010197-8b24-4054-b04a-77fad547fe47'	System	11 Aug 2020 00:19:37
User entered 'No interference with activity (1)'	System	11 Aug 2020 00:19:37

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-10T20:19:15', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'c5010197-8b24-4054-b04a-77fad547fe47'	System	11 Aug 2020 00:19:37
User entered 'None (0)'	System	11 Aug 2020 00:19:37

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-10T20:19:19', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'c5010197-8b24-4054-b04a-77fad547fe47'	System	11 Aug 2020 00:19:37
User entered 'None (0)'	System	11 Aug 2020 00:19:37

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-10T20:19:26', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'c5010197-8b24-4054-b04a-77fad547fe47'	System	11 Aug 2020 00:19:37
User entered 'No (N)'	System	11 Aug 2020 00:19:37

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-10T20:19:34', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'c5010197-8b24-4054-b04a-77fad547fe47'	System	11 Aug 2020 00:19:37
User entered '10 Aug 2020 20:19'	System	11 Aug 2020 00:19:37

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 17:35:41

US3372005

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	10 Aug 2020 00:53:23
User entered 'Day 8'	System	10 Aug 2020 00:53:23

US3372005

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:16:55

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-11T20:34:31', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2b141b76-1276-4758-b6b8-de1dfafc95a1' User entered 'None (0)'	System	12 Aug 2020 00:34:46
	System	12 Aug 2020 00:34:46

US3372005

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-11T20:34:41', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2b141b76-1276-4758-b6b8-de1dfafc95a1' User entered '11 Aug 2020 20:34'	System	12 Aug 2020 00:34:46
	System	12 Aug 2020 00:34:46

US3372005

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 00:53:23

US3372005

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 00:53:23

US3372005

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	10 Aug 2020 00:53:23
User entered 'Day 8'	System	10 Aug 2020 00:53:23

US3372005

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-11T20:34:52', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'efa663c6-2446-404a-bf67-d41bbb56f27f' User entered 'No (N)'	System	12 Aug 2020 00:34:59
	System	12 Aug 2020 00:34:59

US3372005

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-08-11T20:34:56', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'efa663c6-2446-404a-bf67-d41bbb56f27f' User entered '11 Aug 2020 20:34'	System	12 Aug 2020 00:34:59
	System	12 Aug 2020 00:34:59

US3372005

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 00:53:23

US3372005

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 00:53:23

US3372005

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	20 Aug 2020 02:11:50

US3372005

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '11 Aug 2020'	Alexandra Arango (b) (4)	20 Aug 2020 02:11:50

US3372005

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	20 Aug 2020 02:11:50

US3372005

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) Alexandra Arango (b) (4)	20 Aug 2020 02:11:50

US3372005

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	20 Aug 2020 23:15:15

US3372005

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User entered 'I'	System	20 Aug 2020 23:15:15

US3372005

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	21 Aug 2020 12:56:45

US3372005

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '18 Aug 2020'	Alexandra Arango (b) (4)	21 Aug 2020 12:56:45

US3372005

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	21 Aug 2020 12:56:45

US3372005

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Alexandra Arango (b) (4)	21 Aug 2020 12:56:45
	(b) (4)	

US3372005

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	21 Aug 2020 12:56:52

US3372005

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:54:01
User entered 'I'	System	21 Aug 2020 12:56:52

US3372005

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	26 Aug 2020 13:15:37

US3372005

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '25 Aug 2020'	(b) (4) Alexandra Arango (b) (4) (b) (4)	26 Aug 2020 13:15:37

US3372005

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	26 Aug 2020 13:15:37

US3372005

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Alexandra Arango (b) (4)	26 Aug 2020 13:15:37

US3372005

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	26 Aug 2020 13:15:41

US3372005

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered 'I'	System	26 Aug 2020 13:15:41

US3372005

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Elena Acosta (b) (4) (b) (4)	15 Sep 2020 19:09:39

US3372005

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	02 Oct 2020 06:54:52
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'data correct as is' (Site from System).	Peter Jacob (b) (4)	25 Sep 2020 18:20:03
Amendment Manager: Query text changed to "Visit 2 System Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates."	(b) (4)	16 Sep 2020 23:39:54
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	15 Sep 2020 19:09:39
User entered '15 Sep 2020'	Elena Acosta (b) (4)	15 Sep 2020 19:09:39

US3372005

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Clinic (Clinic)'	(b) (4) Elena Acosta (b) (4) (b) (4)	15 Sep 2020 19:09:39

US3372005

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered 'VISIT2'	System	15 Sep 2020 19:09:39

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:18:43

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	25 Sep 2020 18:18:43

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '15 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:18:43

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '13:40'	(b) (4) Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:18:43

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered '15 Sep 2020 13:40'	System	25 Sep 2020 18:18:43

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '36.4' C	(b) (4) Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:18:43

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:18:43

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:18:43

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '64'	(b) (4) Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:18:43

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered 'bpm'	System	25 Sep 2020 18:18:43

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '17'	(b) (4) Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:18:43

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered 'breaths/min'	System	25 Sep 2020 18:18:43

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '118'	(b) (4) Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:18:43

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered 'mmHg'	System	25 Sep 2020 18:18:43

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '67'	(b) (4) Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:18:43

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered 'mmHg'	System	25 Sep 2020 18:18:43

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:19:03

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	25 Sep 2020 18:19:03

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '15 Sep 2020'	(b) (4) Peter Jacob (b) (4)	25 Sep 2020 18:19:03

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '16:05'	(b) (4) Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:19:03

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered '15 Sep 2020 16:05'	System	25 Sep 2020 18:19:03

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 07:12:48
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:19:07
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	25 Sep 2020 18:19:03
User entered '35.9' C	Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:19:03

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:19:03

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:19:03

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '65'	(b) (4) Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:19:03

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered 'bpm'	System	25 Sep 2020 18:19:03

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '17'	(b) (4) Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:19:03

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered 'breaths/min'	System	25 Sep 2020 18:19:03

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '119'	(b) (4) Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:19:03

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered 'mmHg'	System	25 Sep 2020 18:19:03

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '77'	(b) (4) Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:19:03

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered 'mmHg'	System	25 Sep 2020 18:19:03

US3372005

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	25 Sep 2020 18:19:15

US3372005

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '15 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:19:15

US3372005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Elena Acosta (b) (4) (b) (4)	15 Sep 2020 19:32:15

US3372005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) Elena Acosta (b) (4) (b) (4)	15 Sep 2020 19:32:15

US3372005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

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)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	Elena Acosta (b) (4)	15 Sep 2020 19:32:15

US3372005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered 'MRNA-1273 OR PLACEBO'	System	15 Sep 2020 19:32:15

US3372005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User closed query 'Per CDM: Date of Exposure is outside of protocol window from visit 1, please review and clarify or update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:43:02
Query 'Per CDM: Date of Exposure is outside of protocol window from visit 1, please review and clarify or update accordingly. ' answered with 'deviation noted, data correct as is' (Site from DM).	Peter Jacob (b) (4) (b) (4)	18 Nov 2020 17:12:36
User opened query 'Per CDM: Date of Exposure is outside of protocol window from visit 1, please review and clarify or update accordingly. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:21:16
User entered '15 Sep 2020'	Elena Acosta (b) (4) (b) (4)	15 Sep 2020 19:32:15

US3372005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '15:28'	(b) (4) Elena Acosta (b) (4) (b) (4)	15 Sep 2020 19:32:15

US3372005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered '15 Sep 2020 15:28'	System	15 Sep 2020 19:32:15

US3372005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4)	15 Sep 2020 19:32:29
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	15 Sep 2020 19:32:29
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	Elena Acosta (b) (4)	15 Sep 2020 19:32:29
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4)	15 Sep 2020 19:32:15
User entered 'Left Arm (LEFT ARM)'	System	15 Sep 2020 19:32:15
	Elena Acosta (b) (4)	15 Sep 2020 19:32:15
	(b) (4)	

US3372005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered 'ONCE'	System	15 Sep 2020 19:32:15

US3372005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered 'INTRAMUSCULAR'	System	15 Sep 2020 19:32:15

US3372005

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	25 Sep 2020 18:19:25

US3372005

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '15 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:19:25

US3372005

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '14:31'	(b) (4) Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:19:25

US3372005

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered '15 Sep 2020 14:31'	System	25 Sep 2020 18:19:25

US3372005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:16:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '15 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:19:35

US3372005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:19:35

US3372005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	25 Sep 2020 18:19:35

US3372005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '14:27'	(b) (4) Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:19:35

US3372005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered '15 Sep 2020 14:27'	System	25 Sep 2020 18:19:35

US3372005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:19:35

US3372005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	25 Sep 2020 18:19:35

US3372005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:19:35

US3372005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered empty.	System	25 Sep 2020 18:19:35

US3372005

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	18 Sep 2020 17:12:28

US3372005

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered '1'	System	18 Sep 2020 17:12:28

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	15 Sep 2020 19:32:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T16:05:30', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '4e3df6f7-6719-467f-9048-496abc9ca02b' User entered 'Yes (Y)'	System	15 Sep 2020 20:06:24
	System	15 Sep 2020 20:06:24

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T16:05:49', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '4e3df6f7-6719-467f-9048-496abc9ca02b' User entered '96.6'	System	15 Sep 2020 20:06:24
	System	15 Sep 2020 20:06:24

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T16:05:55', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '4e3df6f7-6719-467f-9048-496abc9ca02b'	System	15 Sep 2020 20:06:24
User entered 'No (N)'	System	15 Sep 2020 20:06:24

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T16:06:07', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '4e3df6f7-6719-467f-9048-496abc9ca02b' User entered '15 Sep 2020 16:06'	System	15 Sep 2020 20:06:24
	System	15 Sep 2020 20:06:24

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '15 Sep 2020 15:48'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '15 Sep 2020 18:18'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	15 Sep 2020 19:32:15
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T19:16:18', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '29a57c85-9898-46d2-8f46-331b3043c87f' User entered 'Yes (Y)'	System	15 Sep 2020 23:16:57
	System	15 Sep 2020 23:16:57

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T19:16:33', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '29a57c85-9898-46d2-8f46-331b3043c87f' User entered '98.5'	System	15 Sep 2020 23:16:57
	System	15 Sep 2020 23:16:57

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T19:16:41', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '29a57c85-9898-46d2-8f46-331b3043c87f' User entered 'No (N)'	System	15 Sep 2020 23:16:57
	System	15 Sep 2020 23:16:57

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T19:16:54', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '29a57c85-9898-46d2-8f46-331b3043c87f' User entered '15 Sep 2020 19:16'	System	15 Sep 2020 23:16:57
	System	15 Sep 2020 23:16:57

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '15 Sep 2020 19:13'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	15 Sep 2020 19:32:15
User entered 'Day 2'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T00:43:27', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2a556181-f569-42bc-9c4e-6bab29662d15' User entered 'Yes (Y)'	System	17 Sep 2020 04:44:07
	System	17 Sep 2020 04:44:07

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T00:43:40', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2a556181-f569-42bc-9c4e-6bab29662d15' User entered '97.8'	System	17 Sep 2020 04:44:07
	System	17 Sep 2020 04:44:07

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T00:43:48', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2a556181-f569-42bc-9c4e-6bab29662d15'	System	17 Sep 2020 04:44:07
User entered 'No (N)'	System	17 Sep 2020 04:44:07

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T00:44:04', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2a556181-f569-42bc-9c4e-6bab29662d15' User entered '17 Sep 2020 00:44'	System	17 Sep 2020 04:44:07
	System	17 Sep 2020 04:44:07

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	15 Sep 2020 19:32:15
User entered 'Day 3'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T12:29:49', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '35147fdf-ce5f-42ae-b987-265405f0546a' User entered 'Yes (Y)'	System	17 Sep 2020 16:30:11
	System	17 Sep 2020 16:30:11

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T12:29:55', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '35147fdf-ce5f-42ae-b987-265405f0546a' User entered '97.8'	System	17 Sep 2020 16:30:11
	System	17 Sep 2020 16:30:11

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T12:30:01', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '35147fdf-ce5f-42ae-b987-265405f0546a'	System	17 Sep 2020 16:30:11
User entered 'No (N)'	System	17 Sep 2020 16:30:11

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T12:30:08', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '35147fdf-ce5f-42ae-b987-265405f0546a'	System	17 Sep 2020 16:30:11
User entered '17 Sep 2020 12:30'	System	17 Sep 2020 16:30:11

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	15 Sep 2020 19:32:15
User entered 'Day 4'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-18T16:26:10', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '3adbb589-8a1c-4c3a-a034-c317f6e32911' User entered 'Yes (Y)'	System	18 Sep 2020 20:26:39
	System	18 Sep 2020 20:26:39

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-18T16:26:20', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '3adbb589-8a1c-4c3a-a034-c317f6e32911' User entered '97.8'	System	18 Sep 2020 20:26:39
	System	18 Sep 2020 20:26:39

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-18T16:26:25', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '3adbb589-8a1c-4c3a-a034-c317f6e32911' User entered 'No (N)'	System	18 Sep 2020 20:26:39
	System	18 Sep 2020 20:26:39

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-18T16:26:35', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '3adbb589-8a1c-4c3a-a034-c317f6e32911' User entered '18 Sep 2020 16:26'	System	18 Sep 2020 20:26:39
	System	18 Sep 2020 20:26:39

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	15 Sep 2020 19:32:15
User entered 'Day 5'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-19T21:02:20', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '7de289ca-0779-42ef-a7a9-eaa46b14016d' User entered 'Yes (Y)'	System	20 Sep 2020 01:02:41
	System	20 Sep 2020 01:02:41

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-19T21:02:26', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '7de289ca-0779-42ef-a7a9-eaa46b14016d' User entered '97.8'	System	20 Sep 2020 01:02:41
	System	20 Sep 2020 01:02:41

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-19T21:02:32', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '7de289ca-0779-42ef-a7a9-eaa46b14016d' User entered 'No (N)'	System	20 Sep 2020 01:02:41
	System	20 Sep 2020 01:02:41

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-19T21:02:38', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '7de289ca-0779-42ef-a7a9-eaa46b14016d' User entered '19 Sep 2020 21:02'	System	20 Sep 2020 01:02:41
	System	20 Sep 2020 01:02:41

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	15 Sep 2020 19:32:15
User entered 'Day 6'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-20T13:32:59', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'd0740cd2-6606-415c-b19a-3cfbacd30487' User entered 'Yes (Y)'	System	20 Sep 2020 17:33:23
	System	20 Sep 2020 17:33:23

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-20T13:33:05', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'd0740cd2-6606-415c-b19a-3cfbacd30487' User entered '98.0'	System	20 Sep 2020 17:33:23
	System	20 Sep 2020 17:33:23

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-20T13:33:12', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'd0740cd2-6606-415c-b19a-3cfbacd30487'	System	20 Sep 2020 17:33:23
User entered 'No (N)'	System	20 Sep 2020 17:33:23

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-20T13:33:21', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'd0740cd2-6606-415c-b19a-3cfbacd30487' User entered '20 Sep 2020 13:33'	System	20 Sep 2020 17:33:23
	System	20 Sep 2020 17:33:23

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	15 Sep 2020 19:32:15
User entered 'Day 7'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-21T16:29:03', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '85351371-8ab1-41c0-a817-d7e8d9e85f57'	System	21 Sep 2020 20:29:24
User entered 'Yes (Y)'	System	21 Sep 2020 20:29:24

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-21T16:29:08', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '85351371-8ab1-41c0-a817-d7e8d9e85f57' User entered '98.0'	System	21 Sep 2020 20:29:24
	System	21 Sep 2020 20:29:24

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-21T16:29:13', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '85351371-8ab1-41c0-a817-d7e8d9e85f57'	System	21 Sep 2020 20:29:24
User entered 'No (N)'	System	21 Sep 2020 20:29:24

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-21T16:29:21', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '85351371-8ab1-41c0-a817-d7e8d9e85f57'	System	21 Sep 2020 20:29:24
User entered '21 Sep 2020 16:29'	System	21 Sep 2020 20:29:24

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	15 Sep 2020 19:32:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T16:12:20', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '09e9100b-6e4c-4ee8-93f6-2ce4c33e364e' User entered 'None (1)'	System	15 Sep 2020 20:13:29
	System	15 Sep 2020 20:13:29

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T16:12:26', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '09e9100b-6e4c-4ee8-93f6-2ce4c33e364e' User entered 'No (N)'	System	15 Sep 2020 20:13:29
	System	15 Sep 2020 20:13:29

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T16:12:46', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '09e9100b-6e4c-4ee8-93f6-2ce4c33e364e' User entered 'No (N)'	System	15 Sep 2020 20:13:29
	System	15 Sep 2020 20:13:29

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T16:13:05', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '09e9100b-6e4c-4ee8-93f6-2ce4c33e364e' User entered 'None (1)'	System	15 Sep 2020 20:13:29
	System	15 Sep 2020 20:13:29

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T16:13:24', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '09e9100b-6e4c-4ee8-93f6-2ce4c33e364e' User entered '15 Sep 2020 16:13'	System	15 Sep 2020 20:13:29
	System	15 Sep 2020 20:13:29

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '15 Sep 2020 15:48'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '15 Sep 2020 18:18'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	15 Sep 2020 19:32:15
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T19:17:10', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'd543b487-8f61-40ed-bb56-60711f6578fc' User entered 'None (1)'	System	15 Sep 2020 23:18:01
	System	15 Sep 2020 23:18:01

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T19:17:34', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'd543b487-8f61-40ed-bb56-60711f6578fc' User entered 'No (N)'	System	15 Sep 2020 23:18:01
	System	15 Sep 2020 23:18:01

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T19:17:41', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'd543b487-8f61-40ed-bb56-60711f6578fc' User entered 'No (N)'	System	15 Sep 2020 23:18:01
	System	15 Sep 2020 23:18:01

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T19:17:46', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'd543b487-8f61-40ed-bb56-60711f6578fc' User entered 'None (1)'	System	15 Sep 2020 23:18:01
	System	15 Sep 2020 23:18:01

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T19:17:59', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'd543b487-8f61-40ed-bb56-60711f6578fc' User entered '15 Sep 2020 19:17'	System	15 Sep 2020 23:18:01
	System	15 Sep 2020 23:18:01

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '15 Sep 2020 19:13'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	15 Sep 2020 19:32:15
User entered 'Day 2'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T00:44:15', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '05b4ccab-fbb9-4093-8caf-d44d1a09d32a'	System	17 Sep 2020 04:45:14
User entered 'None (1)'	System	17 Sep 2020 04:45:14

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T00:44:19', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '05b4ccab-fbb9-4093-8caf-d44d1a09d32a' User entered 'No (N)'	System	17 Sep 2020 04:45:14
	System	17 Sep 2020 04:45:14

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T00:44:24', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '05b4ccab-fbb9-4093-8caf-d44d1a09d32a' User entered 'No (N)'	System	17 Sep 2020 04:45:14
	System	17 Sep 2020 04:45:14

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T00:44:53', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '05b4ccab-fbb9-4093-8caf-d44d1a09d32a'	System	17 Sep 2020 04:45:14
User entered 'None (1)'	System	17 Sep 2020 04:45:14

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T00:45:09', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '05b4ccab-fbb9-4093-8caf-d44d1a09d32a' User entered '17 Sep 2020 00:45'	System	17 Sep 2020 04:45:14
	System	17 Sep 2020 04:45:14

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	15 Sep 2020 19:32:15
User entered 'Day 3'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T12:30:17', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '3700d189-16b5-484f-bc9f-e7395eeb1f53'	System	17 Sep 2020 16:30:46
User entered 'None (1)'	System	17 Sep 2020 16:30:46

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T12:30:26', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '3700d189-16b5-484f-bc9f-e7395eeb1f53'	System	17 Sep 2020 16:30:46
User entered 'No (N)'	System	17 Sep 2020 16:30:46

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T12:30:30', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '3700d189-16b5-484f-bc9f-e7395eeb1f53'	System	17 Sep 2020 16:30:46
User entered 'No (N)'	System	17 Sep 2020 16:30:46

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T12:30:34', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '3700d189-16b5-484f-bc9f-e7395eeb1f53'	System	17 Sep 2020 16:30:46
User entered 'None (1)'	System	17 Sep 2020 16:30:46

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T12:30:44', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '3700d189-16b5-484f-bc9f-e7395eeb1f53'	System	17 Sep 2020 16:30:46
User entered '17 Sep 2020 12:30'	System	17 Sep 2020 16:30:46

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	15 Sep 2020 19:32:15
User entered 'Day 4'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-18T16:26:42', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'b6e3fbaf-df54-4f46-ab40-413612f630fa'	System	18 Sep 2020 20:27:08
User entered 'None (1)'	System	18 Sep 2020 20:27:08

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-18T16:26:46', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'b6e3fbaf-df54-4f46-ab40-413612f630fa'	System	18 Sep 2020 20:27:08
User entered 'No (N)'	System	18 Sep 2020 20:27:08

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-18T16:26:50', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'b6e3fbaf-df54-4f46-ab40-413612f630fa' User entered 'No (N)'	System	18 Sep 2020 20:27:08
	System	18 Sep 2020 20:27:08

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-18T16:26:55', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'b6e3fbaf-df54-4f46-ab40-413612f630fa' User entered 'None (1)'	System	18 Sep 2020 20:27:08
	System	18 Sep 2020 20:27:08

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-18T16:27:04', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'b6e3fbaf-df54-4f46-ab40-413612f630fa' User entered '18 Sep 2020 16:27'	System	18 Sep 2020 20:27:08
	System	18 Sep 2020 20:27:08

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	15 Sep 2020 19:32:15
User entered 'Day 5'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-19T21:01:33', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '183373cd-be1a-4578-aa3d-b123fc446463'	System	20 Sep 2020 01:02:12
User entered 'None (1)'	System	20 Sep 2020 01:02:12

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-19T21:01:39', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '183373cd-be1a-4578-aa3d-b123fc446463' User entered 'No (N)'	System	20 Sep 2020 01:02:12
	System	20 Sep 2020 01:02:12

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-19T21:01:51', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '183373cd-be1a-4578-aa3d-b123fc446463'	System	20 Sep 2020 01:02:12
User entered 'No (N)'	System	20 Sep 2020 01:02:12

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-19T21:01:56', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '183373cd-be1a-4578-aa3d-b123fc446463'	System	20 Sep 2020 01:02:12
User entered 'None (1)'	System	20 Sep 2020 01:02:12

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-19T21:02:10', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '183373cd-be1a-4578-aa3d-b123fc446463' User entered '19 Sep 2020 21:02'	System	20 Sep 2020 01:02:12
	System	20 Sep 2020 01:02:12

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	15 Sep 2020 19:32:15
User entered 'Day 6'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-20T13:33:27', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '30cda78f-f92b-4f95-a643-4112e30ddfd9'	System	20 Sep 2020 17:33:49
User entered 'None (1)'	System	20 Sep 2020 17:33:49

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-20T13:33:31', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '30cda78f-f92b-4f95-a643-4112e30ddfd9' User entered 'No (N)'	System	20 Sep 2020 17:33:49
	System	20 Sep 2020 17:33:49

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-20T13:33:34', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '30cda78f-f92b-4f95-a643-4112e30ddfd9' User entered 'No (N)'	System	20 Sep 2020 17:33:49
	System	20 Sep 2020 17:33:49

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-20T13:33:37', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '30cda78f-f92b-4f95-a643-4112e30ddfd9'	System	20 Sep 2020 17:33:49
User entered 'None (1)'	System	20 Sep 2020 17:33:49

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-20T13:33:47', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '30cda78f-f92b-4f95-a643-4112e30ddfd9' User entered '20 Sep 2020 13:33'	System	20 Sep 2020 17:33:49
	System	20 Sep 2020 17:33:49

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	15 Sep 2020 19:32:15
User entered 'Day 7'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-21T16:29:27', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'f7981219-09bc-42b7-8042-81af978a9d99'	System	21 Sep 2020 20:29:48
User entered 'None (1)'	System	21 Sep 2020 20:29:48

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-21T16:29:30', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'f7981219-09bc-42b7-8042-81af978a9d99'	System	21 Sep 2020 20:29:48
User entered 'No (N)'	System	21 Sep 2020 20:29:48

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-21T16:29:35', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'f7981219-09bc-42b7-8042-81af978a9d99'	System	21 Sep 2020 20:29:48
User entered 'No (N)'	System	21 Sep 2020 20:29:48

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-21T16:29:39', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'f7981219-09bc-42b7-8042-81af978a9d99'	System	21 Sep 2020 20:29:48
User entered 'None (1)'	System	21 Sep 2020 20:29:48

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-21T16:29:46', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'f7981219-09bc-42b7-8042-81af978a9d99'	System	21 Sep 2020 20:29:48
User entered '21 Sep 2020 16:29'	System	21 Sep 2020 20:29:48

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	15 Sep 2020 19:32:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T16:06:34', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '027762a6-3bda-43cf-9af6-cf892eef00b8' User entered 'None (0)'	System	15 Sep 2020 20:07:28
	System	15 Sep 2020 20:07:28

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T16:06:43', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '027762a6-3bda-43cf-9af6-cf892eef00b8' User entered 'None (0)'	System	15 Sep 2020 20:07:28
	System	15 Sep 2020 20:07:28

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T16:06:48', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '027762a6-3bda-43cf-9af6-cf892eef00b8' User entered 'None (0)'	System	15 Sep 2020 20:07:28
	System	15 Sep 2020 20:07:28

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T16:06:53', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '027762a6-3bda-43cf-9af6-cf892eef00b8' User entered 'None (0)'	System	15 Sep 2020 20:07:28
	System	15 Sep 2020 20:07:28

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T16:06:57', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '027762a6-3bda-43cf-9af6-cf892eef00b8' User entered 'None (0)'	System	15 Sep 2020 20:07:28
	System	15 Sep 2020 20:07:28

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T16:07:01', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '027762a6-3bda-43cf-9af6-cf892eef00b8' User entered 'None (0)'	System	15 Sep 2020 20:07:28
	System	15 Sep 2020 20:07:28

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T16:07:15', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '027762a6-3bda-43cf-9af6-cf892eef00b8' User entered 'No (N)'	System	15 Sep 2020 20:07:28
	System	15 Sep 2020 20:07:28

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T16:07:25', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '027762a6-3bda-43cf-9af6-cf892eef00b8' User entered '15 Sep 2020 16:07'	System	15 Sep 2020 20:07:28
	System	15 Sep 2020 20:07:28

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '15 Sep 2020 15:48'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '15 Sep 2020 18:18'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	15 Sep 2020 19:32:15
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T19:18:08', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '5913ce08-17a7-46e2-a6c0-44c586a7c8d3' User entered 'None (0)'	System	15 Sep 2020 23:18:56
	System	15 Sep 2020 23:18:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T19:18:15', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '5913ce08-17a7-46e2-a6c0-44c586a7c8d3' User entered 'None (0)'	System	15 Sep 2020 23:18:56
	System	15 Sep 2020 23:18:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T19:18:19', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '5913ce08-17a7-46e2-a6c0-44c586a7c8d3' User entered 'None (0)'	System	15 Sep 2020 23:18:56
	System	15 Sep 2020 23:18:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T19:18:22', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '5913ce08-17a7-46e2-a6c0-44c586a7c8d3' User entered 'None (0)'	System	15 Sep 2020 23:18:56
	System	15 Sep 2020 23:18:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T19:18:25', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '5913ce08-17a7-46e2-a6c0-44c586a7c8d3' User entered 'None (0)'	System	15 Sep 2020 23:18:56
	System	15 Sep 2020 23:18:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T19:18:28', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '5913ce08-17a7-46e2-a6c0-44c586a7c8d3' User entered 'None (0)'	System	15 Sep 2020 23:18:56
	System	15 Sep 2020 23:18:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T19:18:37', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '5913ce08-17a7-46e2-a6c0-44c586a7c8d3' User entered 'No (N)'	System	15 Sep 2020 23:18:56
	System	15 Sep 2020 23:18:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-15T19:18:54', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '5913ce08-17a7-46e2-a6c0-44c586a7c8d3' User entered '15 Sep 2020 19:18'	System	15 Sep 2020 23:18:56
	System	15 Sep 2020 23:18:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '15 Sep 2020 19:13'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	15 Sep 2020 19:32:15
User entered 'Day 2'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T00:45:23', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '240c4c58-1354-4a9a-94c4-5624c171020c' User entered 'None (0)'	System	17 Sep 2020 04:46:17
	System	17 Sep 2020 04:46:17

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T00:45:28', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '240c4c58-1354-4a9a-94c4-5624c171020c' User entered 'None (0)'	System	17 Sep 2020 04:46:17
	System	17 Sep 2020 04:46:17

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T00:45:33', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '240c4c58-1354-4a9a-94c4-5624c171020c' User entered 'None (0)'	System	17 Sep 2020 04:46:17
	System	17 Sep 2020 04:46:17

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T00:45:36', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '240c4c58-1354-4a9a-94c4-5624c171020c' User entered 'None (0)'	System	17 Sep 2020 04:46:17
	System	17 Sep 2020 04:46:17

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T00:45:40', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '240c4c58-1354-4a9a-94c4-5624c171020c' User entered 'None (0)'	System	17 Sep 2020 04:46:17
	System	17 Sep 2020 04:46:17

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T00:45:44', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '240c4c58-1354-4a9a-94c4-5624c171020c' User entered 'None (0)'	System	17 Sep 2020 04:46:17
	System	17 Sep 2020 04:46:17

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T00:45:54', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '240c4c58-1354-4a9a-94c4-5624c171020c' User entered 'No (N)'	System	17 Sep 2020 04:46:17
	System	17 Sep 2020 04:46:17

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T00:46:15', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '240c4c58-1354-4a9a-94c4-5624c171020c' User entered '17 Sep 2020 00:46'	System	17 Sep 2020 04:46:17
	System	17 Sep 2020 04:46:17

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	15 Sep 2020 19:32:15
User entered 'Day 3'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T12:30:50', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '129b424d-bf31-4b08-815c-8d060dad8619' User entered 'None (0)'	System	17 Sep 2020 16:31:42
	System	17 Sep 2020 16:31:42

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T12:30:54', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '129b424d-bf31-4b08-815c-8d060dad8619' User entered 'None (0)'	System	17 Sep 2020 16:31:42
	System	17 Sep 2020 16:31:42

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T12:30:57', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '129b424d-bf31-4b08-815c-8d060dad8619' User entered 'None (0)'	System	17 Sep 2020 16:31:42
	System	17 Sep 2020 16:31:42

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T12:31:04', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '129b424d-bf31-4b08-815c-8d060dad8619' User entered 'None (0)'	System	17 Sep 2020 16:31:42
	System	17 Sep 2020 16:31:42

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T12:31:08', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '129b424d-bf31-4b08-815c-8d060dad8619' User entered 'None (0)'	System	17 Sep 2020 16:31:42
	System	17 Sep 2020 16:31:42

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T12:31:11', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '129b424d-bf31-4b08-815c-8d060dad8619' User entered 'None (0)'	System	17 Sep 2020 16:31:42
	System	17 Sep 2020 16:31:42

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T12:31:20', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '129b424d-bf31-4b08-815c-8d060dad8619' User entered 'No (N)'	System	17 Sep 2020 16:31:42
	System	17 Sep 2020 16:31:42

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-17T12:31:37', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '129b424d-bf31-4b08-815c-8d060dad8619' User entered '17 Sep 2020 12:31'	System	17 Sep 2020 16:31:42
	System	17 Sep 2020 16:31:42

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	15 Sep 2020 19:32:15
User entered 'Day 4'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-18T16:27:13', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '1772be91-4a5c-4259-8108-cf15902d798c' User entered 'None (0)'	System	18 Sep 2020 20:27:56
	System	18 Sep 2020 20:27:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-18T16:27:19', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '1772be91-4a5c-4259-8108-cf15902d798c' User entered 'None (0)'	System	18 Sep 2020 20:27:56
	System	18 Sep 2020 20:27:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-18T16:27:22', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '1772be91-4a5c-4259-8108-cf15902d798c' User entered 'None (0)'	System	18 Sep 2020 20:27:56
	System	18 Sep 2020 20:27:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-18T16:27:25', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '1772be91-4a5c-4259-8108-cf15902d798c' User entered 'None (0)'	System	18 Sep 2020 20:27:56
	System	18 Sep 2020 20:27:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-18T16:27:28', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '1772be91-4a5c-4259-8108-cf15902d798c' User entered 'None (0)'	System	18 Sep 2020 20:27:56
	System	18 Sep 2020 20:27:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-18T16:27:32', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '1772be91-4a5c-4259-8108-cf15902d798c' User entered 'None (0)'	System	18 Sep 2020 20:27:56
	System	18 Sep 2020 20:27:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-18T16:27:35', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '1772be91-4a5c-4259-8108-cf15902d798c' User entered 'No (N)'	System	18 Sep 2020 20:27:56
	System	18 Sep 2020 20:27:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-18T16:27:54', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '1772be91-4a5c-4259-8108-cf15902d798c' User entered '18 Sep 2020 16:27'	System	18 Sep 2020 20:27:56
	System	18 Sep 2020 20:27:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	15 Sep 2020 19:32:15
User entered 'Day 5'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-19T21:02:46', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2e31f04e-65e0-4ccb-8324-6e6eebd307b5' User entered 'None (0)'	System	20 Sep 2020 01:03:24
	System	20 Sep 2020 01:03:24

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-19T21:02:50', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2e31f04e-65e0-4ccb-8324-6e6eebd307b5' User entered 'None (0)'	System	20 Sep 2020 01:03:24
	System	20 Sep 2020 01:03:24

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-19T21:02:52', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2e31f04e-65e0-4ccb-8324-6e6eebd307b5' User entered 'None (0)'	System	20 Sep 2020 01:03:24
	System	20 Sep 2020 01:03:24

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-19T21:02:55', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2e31f04e-65e0-4ccb-8324-6e6eebd307b5' User entered 'None (0)'	System	20 Sep 2020 01:03:24
	System	20 Sep 2020 01:03:24

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-19T21:02:59', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2e31f04e-65e0-4ccb-8324-6e6eebd307b5' User entered 'None (0)'	System	20 Sep 2020 01:03:24
	System	20 Sep 2020 01:03:24

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-19T21:03:02', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2e31f04e-65e0-4ccb-8324-6e6eebd307b5' User entered 'None (0)'	System	20 Sep 2020 01:03:24
	System	20 Sep 2020 01:03:24

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-19T21:03:08', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2e31f04e-65e0-4ccb-8324-6e6eebd307b5' User entered 'No (N)'	System	20 Sep 2020 01:03:24
	System	20 Sep 2020 01:03:24

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-19T21:03:23', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2e31f04e-65e0-4ccb-8324-6e6eebd307b5' User entered '19 Sep 2020 21:03'	System	20 Sep 2020 01:03:24
	System	20 Sep 2020 01:03:24

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	15 Sep 2020 19:32:15
User entered 'Day 6'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-20T13:33:52', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2cd02a93-859e-4c3d-a981-ea7e37f590de' User entered 'None (0)'	System	20 Sep 2020 17:34:37
	System	20 Sep 2020 17:34:37

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-20T13:33:55', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2cd02a93-859e-4c3d-a981-ea7e37f590de' User entered 'None (0)'	System	20 Sep 2020 17:34:37
	System	20 Sep 2020 17:34:37

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-20T13:33:58', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2cd02a93-859e-4c3d-a981-ea7e37f590de' User entered 'None (0)'	System	20 Sep 2020 17:34:37
	System	20 Sep 2020 17:34:37

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-20T13:34:03', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2cd02a93-859e-4c3d-a981-ea7e37f590de' User entered 'None (0)'	System	20 Sep 2020 17:34:37
	System	20 Sep 2020 17:34:37

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-20T13:34:07', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2cd02a93-859e-4c3d-a981-ea7e37f590de' User entered 'None (0)'	System	20 Sep 2020 17:34:37
	System	20 Sep 2020 17:34:37

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-20T13:34:11', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2cd02a93-859e-4c3d-a981-ea7e37f590de' User entered 'None (0)'	System	20 Sep 2020 17:34:37
	System	20 Sep 2020 17:34:37

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-20T13:34:16', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2cd02a93-859e-4c3d-a981-ea7e37f590de' User entered 'No (N)'	System	20 Sep 2020 17:34:37
	System	20 Sep 2020 17:34:37

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-20T13:34:34', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2cd02a93-859e-4c3d-a981-ea7e37f590de' User entered '20 Sep 2020 13:34'	System	20 Sep 2020 17:34:37
	System	20 Sep 2020 17:34:37

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	15 Sep 2020 19:32:15
User entered 'Day 7'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-21T16:29:55', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'd4e1715e-1fe5-41bf-a5e2-0203f72838ef' User entered 'None (0)'	System	21 Sep 2020 20:30:30
	System	21 Sep 2020 20:30:30

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-21T16:29:58', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'd4e1715e-1fe5-41bf-a5e2-0203f72838ef' User entered 'None (0)'	System	21 Sep 2020 20:30:30
	System	21 Sep 2020 20:30:30

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-21T16:30:00', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'd4e1715e-1fe5-41bf-a5e2-0203f72838ef' User entered 'None (0)'	System	21 Sep 2020 20:30:30
	System	21 Sep 2020 20:30:30

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-21T16:30:04', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'd4e1715e-1fe5-41bf-a5e2-0203f72838ef' User entered 'None (0)'	System	21 Sep 2020 20:30:30
	System	21 Sep 2020 20:30:30

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-21T16:30:06', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'd4e1715e-1fe5-41bf-a5e2-0203f72838ef' User entered 'None (0)'	System	21 Sep 2020 20:30:30

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-21T16:30:09', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'd4e1715e-1fe5-41bf-a5e2-0203f72838ef' User entered 'None (0)'	System	21 Sep 2020 20:30:30
	System	21 Sep 2020 20:30:30

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:55

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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-21T16:30:13', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'd4e1715e-1fe5-41bf-a5e2-0203f72838ef' User entered 'No (N)'	System	21 Sep 2020 20:30:30
	System	21 Sep 2020 20:30:30

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-09-21T16:30:27', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'd4e1715e-1fe5-41bf-a5e2-0203f72838ef' User entered '21 Sep 2020 16:30'	System	21 Sep 2020 20:30:30
	System	21 Sep 2020 20:30:30

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 19:32:15

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 19:32:15

US3372005

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4)	
	System	04 Oct 2020 14:01:12
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	04 Oct 2020 13:01:14
User entered 'No (N)' reason for change: New Information	David Scott (b) (4)	04 Oct 2020 13:01:14
	(b) (4)	
User entered 'Yes (Y)'	Alexandra Arango (b) (4)	18 Sep 2020 17:12:59
	(b) (4)	

US3372005

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty; reason for change Data Entry Error	David Scott (b) (4)	04 Oct 2020 13:01:14
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) (6)	21 Sep 2020 06:59:08
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 completed within window per protocol.' (Site from System).	Alexandra Arango (b) (4)	18 Sep 2020 17:13:35
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	18 Sep 2020 17:12:59
User entered '18 Sep 2020'	Alexandra Arango (b) (4)	18 Sep 2020 17:12:59

US3372005

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty; reason for change Data Entry Error	(b) (4)	
	David Scott (b) (4)	04 Oct 2020 14:01:12
	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	David Scott (b) (4)	04 Oct 2020 13:01:14
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Alexandra Arango (b) (4)	18 Sep 2020 17:12:59
	(b) (4)	

US3372005

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	(b) (4)	04 Oct 2020 13:02:07
Please review and reconcile.' (Site from System).		
User entered 'Data entered on incorrect visit. Patient's Day 2 delayed' reason for change: Data Entry Error	David Scott (b) (4)	04 Oct 2020 13:02:07
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	(b) (4)	
Please review and reconcile.' (Site from System).		
User entered empty.	System	04 Oct 2020 13:01:14
	Alexandra Arango (b) (4)	18 Sep 2020 17:12:59
	(b) (4)	

US3372005

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	18 Sep 2020 17:13:40

US3372005

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered 'I'	System	18 Sep 2020 17:13:40

US3372005

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) David Scott (b) (4) (b) (4)	04 Oct 2020 13:00:39

US3372005

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
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)	12 Oct 2020 11:00:41
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'per monitor we were told to stay on schedule and make the calls based on Visit 1 treatment date' (Site from System).	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 18:07:23
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	04 Oct 2020 13:00:39
User entered '16 Sep 2020'	David Scott (b) (4) (b) (4)	04 Oct 2020 13:00:39

US3372005

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) David Scott (b) (4)	04 Oct 2020 13:00:39

US3372005

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) David Scott (b) (4) (b) (4)	04 Oct 2020 13:00:39

US3372005

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	23 Sep 2020 22:47:20

US3372005

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered 'I'	System	23 Sep 2020 22:47:20

US3372005

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	23 Sep 2020 22:47:30

US3372005

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
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)	24 Sep 2020 06:58:44
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 was completed within window per protocol.' (Site from System).	Alexandra Arango (b) (4) (b) (4)	23 Sep 2020 22:47:43
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	23 Sep 2020 22:47:30
User entered '22 Sep 2020'	Alexandra Arango (b) (4) (b) (4)	23 Sep 2020 22:47:30

US3372005

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	23 Sep 2020 22:47:30

US3372005

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) Alexandra Arango (b) (4)	23 Sep 2020 22:47:30
	(b) (4)	

US3372005

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	23 Sep 2020 22:47:54

US3372005

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered 'I'	System	23 Sep 2020 22:47:54

US3372005

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	29 Sep 2020 15:26:34

US3372005

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
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)	
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.'	(b) (4), (b) (6)	02 Oct 2020 06:53:00
answered with 'Date is correct. ' (Site from System).		
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	Kimarie Lee-Russell	29 Sep 2020 15:27:16
User entered '29 Sep 2020'	(b) (4)	
	System	29 Sep 2020 15:26:34
	Kimarie Lee-Russell	29 Sep 2020 15:26:34
	(b) (4)	

US3372005

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Clinic (Clinic)'	(b) (4) Kimarie Lee-Russell (b) (4)	29 Sep 2020 15:26:34

US3372005

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered 'VISIT3'	System	29 Sep 2020 15:26:34

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered empty.	System	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) Peter Jacob (b) (4)	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) Peter Jacob (b) (4)	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered empty.	System	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered empty.	System	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered empty.	System	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered empty.	System	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54

US3372005

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	15 Oct 2020 16:27:37
User entered 'Yes (Y)'	Peter Jacob (b) (4)	09 Oct 2020 15:53:20
	(b) (4)	

US3372005

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty; reason for change Data Entry Error	(b) (4)	
	Peter Jacob (b) (4)	15 Oct 2020 16:27:37
User entered '29 Sep 2020'	(b) (4)	
	Peter Jacob (b) (4)	09 Oct 2020 15:53:20
	(b) (4)	

US3372005

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	09 Oct 2020 15:53:32

US3372005

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '29 Sep 2020'	(b) (4) Peter Jacob (b) (4)	09 Oct 2020 15:53:32

US3372005

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '11:42'	Peter Jacob (b) (4)	09 Oct 2020 15:53:32

US3372005

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered '29 Sep 2020 11:42'	System	09 Oct 2020 15:53:32

US3372005

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:53:37

US3372005

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered 'I'	System	09 Oct 2020 15:53:37

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 64'	System	04 Aug 2020 17:35:41

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-10-06T12:00:52', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '158b4fd3-42a0-47b4-83d3-9f7a62752f50'	System	06 Oct 2020 16:02:30
User entered 'No (N)'	System	06 Oct 2020 16:02:30

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Have you been exposed to someone with 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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-10-06T12:00:57', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '158b4fd3-42a0-47b4-83d3-9f7a62752f50'	System	06 Oct 2020 16:02:30
User entered 'No (N)'	System	06 Oct 2020 16:02:30

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-10-06T12:01:07', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '158b4fd3-42a0-47b4-83d3-9f7a62752f50' User entered '06 Oct 2020 12:01:07'	System	06 Oct 2020 16:02:30
	System	06 Oct 2020 16:02:30

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered '04 Oct 2020 00:01'	System	04 Aug 2020 17:35:41

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered '08 Oct 2020 23:59'	System	04 Aug 2020 17:35:41

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 71'	System	04 Aug 2020 17:35:41

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-10-13T12:01:31', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'bc22dd53-5486-4194-942d-69da1c743d95'	System	13 Oct 2020 16:02:44
User entered 'No (N)'	System	13 Oct 2020 16:02:44

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-10-13T12:01:36', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'bc22dd53-5486-4194-942d-69da1c743d95'	System	13 Oct 2020 16:02:44
User entered 'No (N)'	System	13 Oct 2020 16:02:44

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-10-13T12:01:46', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'bc22dd53-5486-4194-942d-69da1c743d95'	System	13 Oct 2020 16:02:44
User entered '13 Oct 2020 12:01:46'	System	13 Oct 2020 16:02:44

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered '11 Oct 2020 00:01'	System	04 Aug 2020 17:35:41

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered '15 Oct 2020 23:59'	System	04 Aug 2020 17:35:41

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 78'	System	04 Aug 2020 17:35:41

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-10-20T15:03:27', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'f7853f6d-9ef4-4e5b-a852-4d7341c6b7e3'	System	20 Oct 2020 19:04:20
User entered 'No (N)'	System	20 Oct 2020 19:04:20

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-10-20T15:03:42', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'f7853f6d-9ef4-4e5b-a852-4d7341c6b7e3'	System	20 Oct 2020 19:04:20
User entered 'No (N)'	System	20 Oct 2020 19:04:20

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-10-20T15:03:49', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'f7853f6d-9ef4-4e5b-a852-4d7341c6b7e3' User entered '20 Oct 2020 15:03:49'	System	20 Oct 2020 19:04:20
	System	20 Oct 2020 19:04:20

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered '18 Oct 2020 00:01'	System	04 Aug 2020 17:35:41

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered '22 Oct 2020 23:59'	System	04 Aug 2020 17:35:41

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 92'	System	04 Aug 2020 17:35:41

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-11-01T21:47:47', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2444cfd6-15a6-4095-ad32-cefb00788a78' User entered 'No (N)'	System	02 Nov 2020 02:48:16
	System	02 Nov 2020 02:48:16

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-11-01T21:47:53', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2444cfd6-15a6-4095-ad32-cefb00788a78'	System	02 Nov 2020 02:48:16
User entered 'No (N)'	System	02 Nov 2020 02:48:16

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-11-01T21:48:10', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2444cfd6-15a6-4095-ad32-cefb00788a78' User entered '01 Nov 2020 21:48:10'	System	02 Nov 2020 02:48:16
	System	02 Nov 2020 02:48:16

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered '01 Nov 2020 00:01'	System	04 Aug 2020 17:35:41

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered '05 Nov 2020 23:59'	System	04 Aug 2020 17:35:41

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 99'	System	04 Aug 2020 17:35:41

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-11-09T22:21:05', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'f9486f71-80d4-4e54-acc5-820956520e22'	System	10 Nov 2020 03:21:28
User entered 'No (N)'	System	10 Nov 2020 03:21:28

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-11-09T22:21:15', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'f9486f71-80d4-4e54-acc5-820956520e22'	System	10 Nov 2020 03:21:28
User entered 'No (N)'	System	10 Nov 2020 03:21:28

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-11-09T22:21:24', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'f9486f71-80d4-4e54-acc5-820956520e22' User entered '09 Nov 2020 22:21:24'	System	10 Nov 2020 03:21:28
	System	10 Nov 2020 03:21:28

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered '08 Nov 2020 00:01'	System	04 Aug 2020 17:35:41

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered '12 Nov 2020 23:59'	System	04 Aug 2020 17:35:41

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered 'Day 106'	System	04 Aug 2020 17:35:41

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-11-16T22:23:49', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'f26eca61-0165-40a2-afa5-e361b263e082'	System	17 Nov 2020 03:24:05
User entered 'No (N)'	System	17 Nov 2020 03:24:05

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-11-16T22:23:53', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'f26eca61-0165-40a2-afa5-e361b263e082'	System	17 Nov 2020 03:24:05
User entered 'No (N)'	System	17 Nov 2020 03:24:05

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-11-16T22:24:02', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'f26eca61-0165-40a2-afa5-e361b263e082'	System	17 Nov 2020 03:24:05
User entered '16 Nov 2020 22:24:02'	System	17 Nov 2020 03:24:05

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered '15 Nov 2020 00:01'	System	04 Aug 2020 17:35:41

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:00:14
Data entry locked.	System	04 Aug 2020 17:35:41
User entered '19 Nov 2020 23:59'	System	04 Aug 2020 17:35:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-11-19T23:34:31', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '97c54382-0851-41a4-b480-e5776c69b7cd' User entered 'No (N)'	System	20 Nov 2020 04:34:45

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-11-19T23:34:38', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '97c54382-0851-41a4-b480-e5776c69b7cd' User entered 'No (N)'	System	20 Nov 2020 04:34:45

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-11-19T23:34:41', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '97c54382-0851-41a4-b480-e5776c69b7cd' User entered '19 Nov 2020 23:34:41'	System	20 Nov 2020 04:34:45

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-11-26T22:05:11', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '9179fd97-7dd8-4f84-b773-58d4ff3c9cba' User entered 'No (N)'	System	27 Nov 2020 03:05:33

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Have you been exposed to someone with 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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-11-26T22:05:16', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '9179fd97-7dd8-4f84-b773-58d4ff3c9cba'	System	27 Nov 2020 03:05:33
User entered 'No (N)'	System	27 Nov 2020 03:05:33

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-11-26T22:05:29', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '9179fd97-7dd8-4f84-b773-58d4ff3c9cba' User entered '26 Nov 2020 22:05:29'	System	27 Nov 2020 03:05:33
	System	27 Nov 2020 03:05:33

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-12-05T12:16:06', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '89bcf801-d537-41a4-93dc-ee0fb04542d4' User entered 'No (N)'	System	05 Dec 2020 17:16:20
	System	05 Dec 2020 17:16:20

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-12-05T12:16:12', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '89bcf801-d537-41a4-93dc-ee0fb04542d4' User entered 'No (N)'	System	05 Dec 2020 17:16:20
	System	05 Dec 2020 17:16:20

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-12-05T12:16:17', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '89bcf801-d537-41a4-93dc-ee0fb04542d4' User entered '05 Dec 2020 12:16:17'	System	05 Dec 2020 17:16:20
	System	05 Dec 2020 17:16:20

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-12-10T22:16:31', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'da98eebe-799e-4287-afbe-07276e4991cf' User entered 'No (N)'	System	11 Dec 2020 03:16:48
	System	11 Dec 2020 03:16:48

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-12-10T22:16:35', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'da98eebe-799e-4287-afbe-07276e4991cf' User entered 'No (N)'	System	11 Dec 2020 03:16:48
	System	11 Dec 2020 03:16:48

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-12-10T22:16:43', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'da98eebe-799e-4287-afbe-07276e4991cf' User entered '10 Dec 2020 22:16:43'	System	11 Dec 2020 03:16:48
	System	11 Dec 2020 03:16:48

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-12-17T22:00:56', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '1bc4c972-35ec-49b1-9346-64131571fe2a' User entered 'No (N)'	System	18 Dec 2020 03:01:19
	System	18 Dec 2020 03:01:19

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-12-17T22:01:02', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '1bc4c972-35ec-49b1-9346-64131571fe2a' User entered 'No (N)'	System	18 Dec 2020 03:01:19
	System	18 Dec 2020 03:01:19

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-12-17T22:01:12', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '1bc4c972-35ec-49b1-9346-64131571fe2a' User entered '17 Dec 2020 22:01:12'	System	18 Dec 2020 03:01:19
	System	18 Dec 2020 03:01:19

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-12-27T03:42:35', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '1a898d22-c221-4cf1-910f-ae48d6e551e1' User entered 'No (N)'	System	27 Dec 2020 08:42:49
	System	27 Dec 2020 08:42:49

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-12-27T03:42:40', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '1a898d22-c221-4cf1-910f-ae48d6e551e1' User entered 'No (N)'	System	27 Dec 2020 08:42:49

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-12-27T03:42:46', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '1a898d22-c221-4cf1-910f-ae48d6e551e1' User entered '27 Dec 2020 03:42:46'	System	27 Dec 2020 08:42:49
	System	27 Dec 2020 08:42:49

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-12-31T23:55:26', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '67058706-15a5-4d19-a2d0-4bad97c096c3'	System	01 Jan 2021 04:55:43
User entered 'No (N)'	System	01 Jan 2021 04:55:43

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Have you been exposed to someone with 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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-12-31T23:55:31', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '67058706-15a5-4d19-a2d0-4bad97c096c3'	System	01 Jan 2021 04:55:43
User entered 'No (N)'	System	01 Jan 2021 04:55:43

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2020-12-31T23:55:39', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '67058706-15a5-4d19-a2d0-4bad97c096c3' User entered '31 Dec 2020 23:55:39'	System	01 Jan 2021 04:55:43

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-01-07T21:27:00', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '9db0499f-1291-4cd8-b2e1-1eec0258b8de' User entered 'No (N)'	System	08 Jan 2021 02:27:19
	System	08 Jan 2021 02:27:19

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Have you been exposed to someone with 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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-01-07T21:27:04', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '9db0499f-1291-4cd8-b2e1-1eec0258b8de' User entered 'No (N)'	System	08 Jan 2021 02:27:19
	System	08 Jan 2021 02:27:19

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-01-07T21:27:15', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '9db0499f-1291-4cd8-b2e1-1eec0258b8de' User entered '07 Jan 2021 21:27:15'	System	08 Jan 2021 02:27:19
	System	08 Jan 2021 02:27:19

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-01-14T21:43:02', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2d362a97-3570-4718-aa07-6d347d0baf4c' User entered 'No (N)'	System	15 Jan 2021 02:43:22
	System	15 Jan 2021 02:43:22

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-01-14T21:43:08', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2d362a97-3570-4718-aa07-6d347d0baf4c'	System	15 Jan 2021 02:43:22
User entered 'No (N)'	System	15 Jan 2021 02:43:22

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-01-14T21:43:19', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2d362a97-3570-4718-aa07-6d347d0baf4c' User entered '14 Jan 2021 21:43:19'	System	15 Jan 2021 02:43:22

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-01-21T20:25:12', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '07fc31b9-a86f-4124-870c-ae29e2f9a1a5'	System	22 Jan 2021 01:25:36
User entered 'No (N)'	System	22 Jan 2021 01:25:36

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Have you been exposed to someone with 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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-01-21T20:25:19', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '07fc31b9-a86f-4124-870c-ae29e2f9a1a5'	System	22 Jan 2021 01:25:36
User entered 'No (N)'	System	22 Jan 2021 01:25:36

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-01-21T20:25:32', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '07fc31b9-a86f-4124-870c-ae29e2f9a1a5' User entered '21 Jan 2021 20:25:32'	System	22 Jan 2021 01:25:36
	System	22 Jan 2021 01:25:36

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-01-28T07:00:00', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'ea17f6c0-4bf6-453d-a0ad-456abbec5a92'	System	28 Jan 2021 12:00:22
User entered 'No (N)'	System	28 Jan 2021 12:00:22

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Have you been exposed to someone with 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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-01-28T07:00:06', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'ea17f6c0-4bf6-453d-a0ad-456abbec5a92'	System	28 Jan 2021 12:00:22
User entered 'No (N)'	System	28 Jan 2021 12:00:22

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-01-28T07:00:17', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'ea17f6c0-4bf6-453d-a0ad-456abbec5a92'	System	28 Jan 2021 12:00:22
User entered '28 Jan 2021 07:00:17'	System	28 Jan 2021 12:00:22

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-02-04T20:47:14', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'd89c5ab8-d2e4-47e8-a57c-9000775af1e0'	System	05 Feb 2021 01:47:27
User entered 'No (N)'	System	05 Feb 2021 01:47:27

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Have you been exposed to someone with 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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-02-04T20:47:19', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'd89c5ab8-d2e4-47e8-a57c-9000775af1e0'	System	05 Feb 2021 01:47:27
User entered 'No (N)'	System	05 Feb 2021 01:47:27

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-02-04T20:47:25', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'd89c5ab8-d2e4-47e8-a57c-9000775af1e0' User entered '04 Feb 2021 20:47:25'	System	05 Feb 2021 01:47:27
	System	05 Feb 2021 01:47:27

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-02-11T12:26:51', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'c9c4d6c7-a5b3-4a64-975d-3075b43f53c1'	System	11 Feb 2021 17:27:19
User entered 'No (N)'	System	11 Feb 2021 17:27:19

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-02-11T12:26:55', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'c9c4d6c7-a5b3-4a64-975d-3075b43f53c1' User entered 'No (N)'	System	11 Feb 2021 17:27:19
	System	11 Feb 2021 17:27:19

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-02-11T12:27:03', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'c9c4d6c7-a5b3-4a64-975d-3075b43f53c1' User entered '11 Feb 2021 12:27:03'	System	11 Feb 2021 17:27:19
	System	11 Feb 2021 17:27:19

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-02-18T23:40:59', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'df25d310-fc13-4bbc-abdc-182541fc6e8b' User entered 'No (N)'	System	19 Feb 2021 04:41:14
	System	19 Feb 2021 04:41:14

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-02-18T23:41:06', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'df25d310-fc13-4bbc-abdc-182541fc6e8b'	System	19 Feb 2021 04:41:14
User entered 'No (N)'	System	19 Feb 2021 04:41:14

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-02-18T23:41:11', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'df25d310-fc13-4bbc-abdc-182541fc6e8b' User entered '18 Feb 2021 23:41:11'	System	19 Feb 2021 04:41:14
	System	19 Feb 2021 04:41:14

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-02-25T15:32:02', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '6a0dc0c3-fd6d-4023-a5d0-b080642d04e0' User entered 'No (N)'	System	26 Feb 2021 03:36:01
	System	26 Feb 2021 03:36:01

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-02-25T15:32:08', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '6a0dc0c3-fd6d-4023-a5d0-b080642d04e0' User entered 'No (N)'	System	26 Feb 2021 03:36:01

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-02-25T15:32:15', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '6a0dc0c3-fd6d-4023-a5d0-b080642d04e0' User entered '25 Feb 2021 15:32:15'	System	26 Feb 2021 03:36:01

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-03-04T21:40:44', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '8f504f91-fa92-4635-97fb-e6efd002efd3'	System	05 Mar 2021 02:42:17
User entered 'No (N)'	System	05 Mar 2021 02:42:17

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Have you been exposed to someone with 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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-03-04T21:40:49', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '8f504f91-fa92-4635-97fb-e6efd002efd3'	System	05 Mar 2021 02:42:17
User entered 'No (N)'	System	05 Mar 2021 02:42:17

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-03-04T21:40:58', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '8f504f91-fa92-4635-97fb-e6efd002efd3'	System	05 Mar 2021 02:42:17
User entered '04 Mar 2021 21:40:58'	System	05 Mar 2021 02:42:17

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-03-11T15:07:23-05:00', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '15db88ac-4253-4326-b5f4-1c9ba1e7c499'	System	11 Mar 2021 20:07:43
User entered 'No (N)'	System	11 Mar 2021 20:07:43

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-03-11T15:07:28-05:00', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '15db88ac-4253-4326-b5f4-1c9ba1e7c499'	System	11 Mar 2021 20:07:43
User entered 'No (N)'	System	11 Mar 2021 20:07:43

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-03-11T15:07:38-05:00', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '15db88ac-4253-4326-b5f4-1c9ba1e7c499'	System	11 Mar 2021 20:07:43
User entered '11 Mar 2021 15:07:38'	System	11 Mar 2021 20:07:43

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-03-18T22:16:46-04:00', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'e9f19e97-3c82-4fa4-b5a7-62f989f32949'	System	19 Mar 2021 02:17:02
User entered 'No (N)'	System	19 Mar 2021 02:17:02

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-03-18T22:16:51-04:00', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'e9f19e97-3c82-4fa4-b5a7-62f989f32949'	System	19 Mar 2021 02:17:02
User entered 'No (N)'	System	19 Mar 2021 02:17:02

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-03-18T22:16:57-04:00', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'e9f19e97-3c82-4fa4-b5a7-62f989f32949'	System	19 Mar 2021 02:17:02
User entered '18 Mar 2021 22:16:57'	System	19 Mar 2021 02:17:02

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-03-25T21:35:39-04:00', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'e66127c1-6e22-4560-8bf6-4ed87c6d9c9e'	System	26 Mar 2021 01:36:42
User entered 'No (N)'	System	26 Mar 2021 01:36:42

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Have you been exposed to someone with 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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-03-25T21:35:43-04:00', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'e66127c1-6e22-4560-8bf6-4ed87c6d9c9e'	System	26 Mar 2021 01:36:42
User entered 'No (N)'	System	26 Mar 2021 01:36:42

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-03-25T21:35:49-04:00', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'e66127c1-6e22-4560-8bf6-4ed87c6d9c9e' User entered '25 Mar 2021 21:35:49'	System	26 Mar 2021 01:36:42
	System	26 Mar 2021 01:36:42

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-04-01T13:06:27-04:00', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'fd5e4b67-66b8-46dc-b990-380612c9d71d' User entered 'No (N)'	System	01 Apr 2021 17:08:02
	System	01 Apr 2021 17:08:02

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-04-01T13:06:32-04:00', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'fd5e4b67-66b8-46dc-b990-380612c9d71d'	System	01 Apr 2021 17:08:02
User entered 'No (N)'	System	01 Apr 2021 17:08:02

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-04-01T13:06:41-04:00', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'fd5e4b67-66b8-46dc-b990-380612c9d71d'	System	01 Apr 2021 17:08:02
User entered '01 Apr 2021 13:06:41'	System	01 Apr 2021 17:08:02

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-04-08T22:49:23-04:00', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '45c46b09-3a95-4c1f-b3a3-4bff2338854c' User entered 'No (N)'	System	09 Apr 2021 02:53:08

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-04-08T22:49:29-04:00', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '45c46b09-3a95-4c1f-b3a3-4bff2338854c'	System	09 Apr 2021 02:53:08
User entered 'No (N)'	System	09 Apr 2021 02:53:08

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-04-08T22:49:44-04:00', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '45c46b09-3a95-4c1f-b3a3-4bff2338854c'	System	09 Apr 2021 02:53:08
User entered '08 Apr 2021 22:49:44'	System	09 Apr 2021 02:53:08

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-04-16T21:28:56-04:00', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '15274738-4445-43ad-92fe-d1f4329245c2'	System	17 Apr 2021 01:29:13
User entered 'No (N)'	System	17 Apr 2021 01:29:13

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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 (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-04-16T21:29:01-04:00', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '15274738-4445-43ad-92fe-d1f4329245c2'	System	17 Apr 2021 01:29:13
User entered 'No (N)'	System	17 Apr 2021 01:29:13

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-04-16T21:29:07-04:00', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '15274738-4445-43ad-92fe-d1f4329245c2'	System	17 Apr 2021 01:29:13
User entered '16 Apr 2021 21:29:07'	System	17 Apr 2021 01:29:13

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 (925B122C-8E6D-4F99-9149-2DDC9858E84D)', Time: '2021-04-22T06:32:52-04:00', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '1304f9f8-7e60-405f-a917-9538756c57f6'	System	22 Apr 2021 10:33:06
User entered 'No (N)'	System	22 Apr 2021 10:33:06

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

Have you been exposed to someone with 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 (925B122C-8E6D-4F99-9149-2DDC9858E84D)', Time: '2021-04-22T06:32:56-04:00', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '1304f9f8-7e60-405f-a917-9538756c57f6'	System	22 Apr 2021 10:33:06
User entered 'No (N)'	System	22 Apr 2021 10:33:06

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925B122C-8E6D-4F99-9149-2DDC9858E84D)', Time: '2021-04-22T06:33:03-04:00', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '1304f9f8-7e60-405f-a917-9538756c57f6'	System	22 Apr 2021 10:33:06
User entered '22 Apr 2021 06:33:03'	System	22 Apr 2021 10:33:06

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[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 (925B122C-8E6D-4F99-9149-2DDC9858E84D)', Time: '2021-04-29T15:02:51-04:00', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'e6bf2c85-11e9-45c7-9e6c-80dfa0ccdc0b' User entered 'No (N)'	System	29 Apr 2021 19:04:04

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Have you been exposed to someone with 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 (925B122C-8E6D-4F99-9149-2DDC9858E84D)', Time: '2021-04-29T15:02:53-04:00', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'e6bf2c85-11e9-45c7-9e6c-80dfa0ccdc0b' User entered 'No (N)'	System	29 Apr 2021 19:04:04

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925B122C-8E6D-4F99-9149-2DDC9858E84D)', Time: '2021-04-29T15:03:01-04:00', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'e6bf2c85-11e9-45c7-9e6c-80dfa0ccdc0b' User entered '29 Apr 2021 15:03:01'	System	29 Apr 2021 19:04:04
	System	29 Apr 2021 19:04:04

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 11:03:41

US3372005

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:16:55

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:44:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-02-27T22:56:07', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'b7678828-8165-4ba0-83f9-a79ff158ae09'	System	28 Feb 2021 03:57:13
User entered 'No (N)'	System	28 Feb 2021 03:57:13

US3372005

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:16:55

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:44:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B18A93C-665B-4ADB-B879-C4218F9EE08E)', Time: '2021-02-27T22:56:14', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'b7678828-8165-4ba0-83f9-a79ff158ae09' User entered '27 Feb 2021 22:56:14'	System	28 Feb 2021 03:57:13
	System	28 Feb 2021 03:57:13

US3372005

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	27 Oct 2020 18:20:15

US3372005

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:10:21
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 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).	Mary Sergalis (b) (4)	28 Oct 2020 17:43:47
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	27 Oct 2020 18:20:15
User entered '27 Oct 2020'	Danielle Theodore (b) (4) (b) (4)	27 Oct 2020 18:20:15

US3372005

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	27 Oct 2020 18:20:15

US3372005

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) Danielle Theodore (b) (4)	27 Oct 2020 18:20:15
	(b) (4)	

US3372005

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	27 Oct 2020 18:20:45

US3372005

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:24:54
User entered 'I'	System	27 Oct 2020 18:20:45

US3372005

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	15 Dec 2020 13:41:33

US3372005

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '15 Dec 2020'	(b) (4) Danielle Theodore (b) (4)	15 Dec 2020 13:41:33

US3372005

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	15 Dec 2020 13:41:33

US3372005

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Danielle Theodore (b) (4)	15 Dec 2020 13:41:33
	(b) (4)	

US3372005

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	15 Dec 2020 13:41:44

US3372005

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User entered 'I'	System	15 Dec 2020 13:41:44

US3372005

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	13 Jan 2021 18:45:39

US3372005

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '13 Jan 2021'	(b) (4) Danielle Theodore (b) (4) (b) (4)	13 Jan 2021 18:45:39

US3372005

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	13 Jan 2021 18:45:39

US3372005

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Danielle Theodore (b) (4)	13 Jan 2021 18:45:39
	(b) (4)	

US3372005

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	13 Jan 2021 18:45:45

US3372005

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User entered 'I'	System	13 Jan 2021 18:45:45

US3372005

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	29 Jan 2021 18:53:35

US3372005

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
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)	01 Feb 2021 15:12:43
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 'data correct as entered' (Site from System).	Danielle Theodore (b) (4) (b) (4)	29 Jan 2021 19:16:06
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	29 Jan 2021 18:53:35
User entered '29 Jan 2021'	Danielle Theodore (b) (4) (b) (4)	29 Jan 2021 18:53:35

US3372005

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	29 Jan 2021 18:53:35

US3372005

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Danielle Theodore (b) (4)	29 Jan 2021 18:53:35
	(b) (4)	

US3372005

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	29 Jan 2021 19:16:14

US3372005

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User entered 'I'	System	29 Jan 2021 19:16:14

US3372005

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	09 Mar 2021 17:06:40

US3372005

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered '8 Mar 2021'	(b) (4) Danielle Theodore (b) (4)	09 Mar 2021 17:06:40
	(b) (4)	

US3372005

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[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 11:14:55
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered 'Clinic (Clinic)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	09 Mar 2021 17:06:40

US3372005

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User entered 'VISIT4'	System	09 Mar 2021 17:06:40

US3372005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	12 Apr 2021 21:31:21
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:54:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 16:54:30
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:06:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:21:43

US3372005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	12 Apr 2021 21:31:21
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:54:30
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 16:54:30
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:06:45
User entered '08 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:21:43

US3372005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	12 Apr 2021 21:31:21
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:54:30
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 16:54:30
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:06:45
User entered '12:04'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:21:43

US3372005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User entered empty.	System	12 Apr 2021 16:54:30
User entered '08 Mar 2021 12:04'	System	30 Mar 2021 17:21:43

US3372005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User closed query 'Per CDM: Please be aware that Participant Decision Visit and OL-D57 took place exactly the same day. However, Vital Signs Temperature is recorded here as 36.7 C but in OL-D57 it is recorded as 98.1 F. Please clarify why there is a difference or update the field. Thank you!' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 06:30:54
User signature succeeded.	Mira Baron (b) (4)	12 Apr 2021 21:31:21
Query 'Per CDM: Please be aware that Participant Decision Visit and OL-D57 took place exactly the same day. However, Vital Signs Temperature is recorded here as 36.7 C but in OL-D57 it is recorded as 98.1 F. Please clarify why there is a difference or update the field. Thank you!' 'answered with 'Data updated. The sponsor does not want duplicate data. So the vitals for Visit 4 Day 209 were removed and the vitals for OL-D57 have been recorded.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:55:39
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 16:54:30
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 16:54:30
User opened query 'Per CDM: Please be aware that Participant Decision Visit and OL-D57 took place exactly the same day. However, Vital Signs Temperature is recorded here as 36.7 C but in OL-D57 it is recorded as 98.1 F. Please clarify why there is a difference or update the field. Thank you!' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 16:40:22
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:06:45
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:21:43

US3372005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	12 Apr 2021 21:31:21
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:54:30
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 16:54:30
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:06:45
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:21:43

US3372005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	12 Apr 2021 21:31:21
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:54:30
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 16:54:30
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:06:45
User entered 'forehead'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:21:43

US3372005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	12 Apr 2021 21:31:21
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:54:30
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 16:54:30
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:06:45
User entered '62'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:21:43

US3372005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User entered empty.	System	12 Apr 2021 16:54:30
User entered 'bpm'	System	30 Mar 2021 17:21:43

US3372005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	12 Apr 2021 21:31:21
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:54:30
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 16:54:30
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:06:45
User entered '17'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:21:43

US3372005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User entered empty.	System	12 Apr 2021 16:54:30
User entered 'breaths/min'	System	30 Mar 2021 17:21:43

US3372005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	12 Apr 2021 21:31:21
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:54:30
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 16:54:30
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:06:45
User entered '137'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:21:43

US3372005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User entered empty.	System	12 Apr 2021 16:54:30
User entered 'mmHg'	System	30 Mar 2021 17:21:43

US3372005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	12 Apr 2021 21:31:21
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:54:30
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 16:54:30
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:06:45
User entered '64'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:21:43

US3372005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User entered empty.	System	12 Apr 2021 16:54:30
User entered 'mmHg'	System	30 Mar 2021 17:21:43

US3372005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55

US3372005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55

US3372005

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered 'No (N)'	(b) (4) Danielle Theodore (b) (4)	09 Mar 2021 17:06:52

US3372005

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered empty.	(b) (4) Danielle Theodore (b) (4)	09 Mar 2021 17:06:52
	(b) (4)	

US3372005

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	09 Mar 2021 17:07:10
	(b) (4)	

US3372005

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered '8 Mar 2021'	(b) (4) Danielle Theodore (b) (4) (b) (4)	09 Mar 2021 17:07:10

US3372005

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered '12:22'	(b) (4) Danielle Theodore (b) (4)	09 Mar 2021 17:07:10
	(b) (4)	

US3372005

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User entered '8 Mar 2021 12:22'	System	09 Mar 2021 17:07:10

US3372005

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	09 Mar 2021 17:07:18

US3372005

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:14:55
User entered 'I'	System	09 Mar 2021 17:07:18

US3372005

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:48:35
	(b) (4)	
User entered 'Yes (Y)'	Danielle Theodore (b) (4)	13 Apr 2021 14:42:01
	(b) (4)	

US3372005

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:48:35
	(b) (4)	
User entered '13 Apr 2021'	Danielle Theodore (b) (4)	13 Apr 2021 14:42:01
	(b) (4)	

US3372005

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:48:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	13 Apr 2021 14:42:01

US3372005

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:48:35
User entered empty.	(b) (4)	
	Danielle Theodore (b) (4)	13 Apr 2021 14:42:01
	(b) (4)	

US3372005

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:48:35
	(b) (4)	
User entered 'Yes (Y)'	Danielle Theodore (b) (4)	13 Apr 2021 14:42:07
	(b) (4)	

US3372005

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 14:42:07

US3372005

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

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 17:48:14

US3372005

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

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 17:48:14

US3372005

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

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[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 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 17:48:14

US3372005

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

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'UNBLND_DECIDE'	System	13 Jan 2021 17:48:14

US3372005

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

Form: Unblinding

Generated On: 09 Jun 2021 17:16:55

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 17:48:38

US3372005

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

Form: Unblinding

Generated On: 09 Jun 2021 17:16:55

[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 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Apr 2021 21:31:21
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:17:48
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:01:29

US3372005

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

Form: Unblinding

Generated On: 09 Jun 2021 17:16:55

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 17:48:38

US3372005

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

Form: Unblinding

Generated On: 09 Jun 2021 17:16:55

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 06:31:05
User signature succeeded.	Mira Baron (b) (4)	12 Apr 2021 21:31:21
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'Data updated.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:18:09
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	12 Apr 2021 18:17:48
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 15:52:18
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:01:29

US3372005

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

Form: Unblinding

Generated On: 09 Jun 2021 17:16:55

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 17:48:38

US3372005

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

Form: Unblinding

Generated On: 09 Jun 2021 17:16:55

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 17:48:38

US3372005

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

Form: Unblinding

Generated On: 09 Jun 2021 17:16:55

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 11:11:27
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	13 Jan 2021 17:48:38

US3372005

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

Form: Unblinding

Generated On: 09 Jun 2021 17:16:55

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 11:11:27
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	13 Jan 2021 17:48:38

US3372005

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

Form: Unblinding

Generated On: 09 Jun 2021 17:16:55

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 17:48:38

US3372005

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

Form: Unblinding

Generated On: 09 Jun 2021 17:16:55

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered '1'	System	13 Jan 2021 17:48:38

US3372005

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

Form: Unblinding

Generated On: 09 Jun 2021 17:16:55

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'I'	System	13 Jan 2021 17:48:38

US3372005

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:55

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:55

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered empty.	System	14 Jan 2021 15:15:49
DataPoint set to visible.	System	13 Jan 2021 17:48:38

US3372005

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:55

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:55

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered empty.	System	14 Jan 2021 15:15:49
DataPoint set to visible.	System	13 Jan 2021 17:48:38

US3372005

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '12:48'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered '8 Jan 2021 12:48'	System	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '59'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'bpm'	System	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '17'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'breaths/min'	System	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '142'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'mmHg'	System	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '79'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'mmHg'	System	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:55

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:55

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered empty.	System	14 Jan 2021 15:15:49
DataPoint set to visible.	System	13 Jan 2021 17:48:38

US3372005

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '14:25'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered '8 Jan 2021 14:25'	System	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '36.5' C	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '62'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'bpm'	System	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '17'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'breaths/min'	System	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '149'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'mmHg'	System	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '92'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:15:49

US3372005

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'mmHg'	System	14 Jan 2021 15:15:49

US3372005

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:15:54

US3372005

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:15:54

US3372005

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

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:16:21

US3372005

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

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:16:21

US3372005

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

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

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 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:16:21

US3372005

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

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'mRNA-1273'	System	14 Jan 2021 15:16:21
DataPoint set to visible.	System	13 Jan 2021 17:48:38

US3372005

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

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:16:21

US3372005

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

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '13:53'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:16:21

US3372005

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

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered '8 Jan 2021 13:53'	System	14 Jan 2021 15:16:21

US3372005

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

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:16:21

US3372005

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

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'ONCE'	System	14 Jan 2021 15:16:21

US3372005

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

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'INTRAMUSCULAR'	System	14 Jan 2021 15:16:21

US3372005

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 17:49:09

US3372005

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 17:49:09

US3372005

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '12:06'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 17:49:09

US3372005

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered '8 Jan 2021 12:06'	System	13 Jan 2021 17:49:09

US3372005

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:16:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 17:49:26

US3372005

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 17:49:26

US3372005

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:16:55

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '12:09'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 17:49:26

US3372005

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:16:55

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered '8 Jan 2021 12:09'	System	13 Jan 2021 17:49:26

US3372005

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

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 17:49:29

US3372005

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

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'I'	System	13 Jan 2021 17:49:29

US3372005

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	15 Jan 2021 14:04:05

US3372005

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '15 Jan 2021'	(b) (4) Danielle Theodore (b) (4)	15 Jan 2021 14:04:05
	(b) (4)	

US3372005

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	15 Jan 2021 14:04:05

US3372005

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) Danielle Theodore (b) (4)	15 Jan 2021 14:04:05
	(b) (4)	

US3372005

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	15 Jan 2021 14:04:11

US3372005

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'I'	System	15 Jan 2021 14:04:11

US3372005

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered '1'	System	15 Jan 2021 14:04:11
DataPoint set to visible.	System	15 Jan 2021 14:04:11

US3372005

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:31:22

US3372005

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '5 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:31:22

US3372005

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[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 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:31:22

US3372005

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'OLD29'	System	08 Feb 2021 14:31:22

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '5 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '11:25'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered '5 Feb 2021 11:25'	System	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '72'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'bpm'	System	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '17'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'breaths/min'	System	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '119'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'mmHg'	System	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '75'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'mmHg'	System	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '5 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '12:35'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered '5 Feb 2021 12:35'	System	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '67'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'bpm'	System	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '16'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'breaths/min'	System	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '110'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'mmHg'	System	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '67'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'mmHg'	System	08 Feb 2021 14:33:03

US3372005

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:33:07

US3372005

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:33:07

US3372005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:33:23

US3372005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:33:23

US3372005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

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 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:33:23

US3372005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'mRNA-1273'	System	08 Feb 2021 14:33:23
DataPoint set to visible.	System	15 Jan 2021 14:04:11

US3372005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '5 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:33:23

US3372005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '12:05'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:33:23

US3372005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered '5 Feb 2021 12:05'	System	08 Feb 2021 14:33:23

US3372005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:33:23

US3372005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'ONCE'	System	08 Feb 2021 14:33:23

US3372005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:55

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'INTRAMUSCULAR'	System	08 Feb 2021 14:33:23

US3372005

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:33:28

US3372005

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'I'	System	08 Feb 2021 14:33:28

US3372005

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	10 Feb 2021 15:56:59

US3372005

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 15:21:23
Signature has been broken.	(b) (4) Danielle Theodore (b) (4)	12 Feb 2021 22:14:16
User entered '12 Feb 2021' reason for change: Data Entry Error	(b) (4) Danielle Theodore (b) (4)	12 Feb 2021 22:14:16
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered '10 Feb 2021'	(b) (4) Danielle Theodore (b) (4)	10 Feb 2021 15:56:59

US3372005

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	10 Feb 2021 15:56:59

US3372005

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered empty.	(b) (4) Danielle Theodore (b) (4)	10 Feb 2021 15:56:59
	(b) (4)	

US3372005

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:14
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	10 Feb 2021 15:57:06
	(b) (4)	

US3372005

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'I'	System	10 Feb 2021 15:57:06

US3372005

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	09 Mar 2021 17:03:04

US3372005

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered '8 Mar 2021'	(b) (4) Danielle Theodore (b) (4)	09 Mar 2021 17:03:04
	(b) (4)	

US3372005

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[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 00:25:28
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered 'Clinic (Clinic)'	(b) (4) Danielle Theodore (b) (4)	09 Mar 2021 17:03:04

US3372005

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'OLD57'	System	09 Mar 2021 17:03:04

US3372005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
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 15:05:50
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 17:22:57
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 14:26:20
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	09 Mar 2021 17:04:48

US3372005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered '8 Mar 2021'	(b) (4) Danielle Theodore (b) (4)	09 Mar 2021 17:04:48
	(b) (4)	

US3372005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered '12:04'	(b) (4) Danielle Theodore (b) (4)	09 Mar 2021 17:04:48
	(b) (4)	

US3372005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered '8 Mar 2021 12:04'	System	09 Mar 2021 17:04:48

US3372005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered '98.1' F	(b) (4) Danielle Theodore (b) (4)	09 Mar 2021 17:04:48

US3372005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered 'Other (Other)'	(b) (4) Danielle Theodore (b) (4)	09 Mar 2021 17:04:48

US3372005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered 'Forehead'	(b) (4) Danielle Theodore (b) (4)	09 Mar 2021 17:04:48

US3372005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered '62'	(b) (4) Danielle Theodore (b) (4) (b) (4)	09 Mar 2021 17:04:48

US3372005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'bpm'	System	09 Mar 2021 17:04:48

US3372005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered '17'	(b) (4) Danielle Theodore (b) (4) (b) (4)	09 Mar 2021 17:04:48

US3372005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'breaths/min'	System	09 Mar 2021 17:04:48

US3372005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered '137'	(b) (4) Danielle Theodore (b) (4)	09 Mar 2021 17:04:48

US3372005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'mmHg'	System	09 Mar 2021 17:04:48

US3372005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered '64'	(b) (4) Danielle Theodore (b) (4)	09 Mar 2021 17:04:48
	(b) (4)	

US3372005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered 'mmHg'	System	09 Mar 2021 17:04:48

US3372005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28

US3372005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28

US3372005

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered 'No (N)'	(b) (4) Danielle Theodore (b) (4)	09 Mar 2021 17:05:18
	(b) (4)	

US3372005

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered empty.	(b) (4) Danielle Theodore (b) (4)	09 Mar 2021 17:05:18

US3372005

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	09 Mar 2021 17:05:34

US3372005

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered '8 Mar 2021'	(b) (4) Danielle Theodore (b) (4)	09 Mar 2021 17:05:34
	(b) (4)	

US3372005

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:23:25
User entered '12:22'	(b) (4) Danielle Theodore (b) (4)	09 Mar 2021 17:05:34
	(b) (4)	

US3372005

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:25:28
User entered '8 Mar 2021 12:22'	System	09 Mar 2021 17:05:34

US3372005

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:16:55

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:05
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:33:47
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	31 Aug 2020 18:40:18

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Sep 2020 13:05:57
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:12:57
User entered	System	31 Aug 2020 20:12:45
'USA-US056-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	31 Aug 2020 20:12:45

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 16:22:27
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Hip fracture, LLT: Fractured hip - version MedDRA\23.0.	Coder Import (b) (4)	19 Oct 2020 21:58:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	19 Oct 2020 21:58:32
Data point term sent to Coder	System	19 Oct 2020 14:34:53
DataPoint Un-verified.	Mary Sergalis (b) (4)	19 Oct 2020 14:34:06
Coding entries removed.	Mary Sergalis (b) (4)	19 Oct 2020 14:34:06
User entered 'FRACTURED Left HIP' reason for change: Data Entry Error	Mary Sergalis (b) (4)	19 Oct 2020 14:34:06
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 13:05:57
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Hip fracture, LLT: Fractured hip - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 19:13:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 19:13:46
Data point term sent to Coder	System	31 Aug 2020 19:12:48
User entered 'Fractured Right Hip'	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:35:46
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
User closed query 'Per sponsor review, SAE resulted in hospitalization but 'Was this a MAAE?' is No. Please review and reconcile. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 10:29:21
Query 'Per sponsor review, SAE resulted in hospitalization but 'Was this a MAAE?' is No. Please review and reconcile. ' answered with 'corrected' (Site from DM).	Mary Sergalis (b) (4)	06 Jan 2021 14:31:20
DataPoint Un-verified.	Mary Sergalis (b) (4)	06 Jan 2021 14:31:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	06 Jan 2021 14:31:06
User opened query 'Per sponsor review, SAE resulted in hospitalization but 'Was this a MAAE?' is No. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 14:53:13
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 13:05:57
Query 'Per ETRTR: Please confirm answer. Refer to Protocol section 8.3.2 to confirm whether this was a MAAE or not, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 18:41:34
User opened query 'Per ETRTR: Please confirm answer. Refer to Protocol section 8.3.2 to confirm whether this was a MAAE or not, thanks.' (Site from CRA).	(b) (4), (b) (6)	01 Sep 2020 19:46:38
User entered 'No (N)'	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:05:57
User entered 'No (N)'	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:05:57
User entered 'No (N)'	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Sep 2020 13:05:57
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	16 Sep 2020 23:39:54
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	15 Sep 2020 19:32:15
User entered '25 Aug 2020'	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Sep 2020 13:05:57
User entered empty.	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 16:22:52
DataPoint Un-verified.	Mary Sergalis (b) (4)	18 Sep 2020 16:01:07
User entered 'No (N)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	18 Sep 2020 16:01:07
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 13:05:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	31 Aug 2020 19:13:55
User entered 'No (N)'	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 16:23:32
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 20:13:13
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'end date entered' (Site from Safety).	Mary Sergalis (b) (4)	18 Sep 2020 16:01:25
DataPoint Un-verified.	Mary Sergalis (b) (4)	18 Sep 2020 16:01:07
User entered '26 Aug 2020' reason for change: Data Entry Error	Mary Sergalis (b) (4)	18 Sep 2020 16:01:07
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 13:05:57
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 22:42:50
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	31 Aug 2020 19:13:55
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	31 Aug 2020 19:13:55
User entered empty; reason for change Data Entry Error	Mary Sergalis (b) (4)	31 Aug 2020 19:13:55
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	31 Aug 2020 19:12:26
User entered '26 Aug 2020'	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:05:57
User entered empty.	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

Severity

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:15:35
User closed query 'PV Query: The event intensity is "Grade 4" for this event. Per the vaccine grading (Grade 4=potential life-threatening; subject was at risk of death at the time of the event). Please provide additional details regarding imminent risk of death and treatment info. Else, please reassess the event intensity grade.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 20:13:10
Query 'PV Query: The event intensity is "Grade 4" for this event. Per the vaccine grading (Grade 4=potential life-threatening; subject was at risk of death at the time of the event). Please provide additional details regarding imminent risk of death and treatment info. Else, please reassess the event intensity grade.' answered with 'Intensity updated' (Site from Safety).	Mary Sergalis (b) (4)	18 Sep 2020 16:01:36
DataPoint Un-verified.	Mary Sergalis (b) (4)	18 Sep 2020 16:01:07
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	18 Sep 2020 16:01:07
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 13:05:57
User opened query 'PV Query: The event intensity is "Grade 4" for this event. Per the vaccine grading (Grade 4=potential life-threatening; subject was at risk of death at the time of the event). Please provide additional details regarding imminent risk of death and treatment info. Else, please reassess the event intensity grade.' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 22:40:35
Query 'Per ETRTR: Please confirm the event severity of grade 4. Was this event considered life-threatening? If no, please consider updating event to grade 3' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 18:41:37
User opened query 'Per ETRTR: Please confirm the event severity of grade 4. Was this event considered life-threatening? If no, please consider updating event to grade 3' (Site from CRA).	(b) (4), (b) (6)	01 Sep 2020 19:47:09

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Severity](#)

Audit	User	Time (GMT)
Query 'Please confirm the event severity of grade 4. Was this event considered life-threatening? If no, please consider updating event to grade 3' canceled (Site from CRA).	(b) (4), (b) (6)	01 Sep 2020 19:47:00
User opened query 'Please confirm the event severity of grade 4. Was this event considered life-threatening? If no, please consider updating event to grade 3' (Site from CRA).	(b) (4), (b) (6)	01 Sep 2020 19:46:58
User entered 'Grade 4 (Grade 4)'	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:05:57
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Sep 2020 13:05:57
User entered '0'	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
User closed query 'Per DM CLR: Other Action Taken = Concomitant Procedure, however there are Concomitant Medications recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM). Query 'Per DM CLR: Other Action Taken = Concomitant Procedure, however there are Concomitant Medications recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'Updated' (Site from DM). User opened query 'Per DM CLR: Other Action Taken = Concomitant Procedure, however there are Concomitant Medications recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6) Mary Sergalis (b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	03 Nov 2020 14:40:01 02 Nov 2020 14:52:30 30 Oct 2020 04:21:38 18 Sep 2020 13:05:57
User entered '0'	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Sep 2020 13:05:57
User entered 'I'	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:29:55
User closed query 'PV Query: It was confirmed that the fall and hospitalization occurred on the same day, 25 Aug 2020. If correct, please update hospitalization date.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:30:33
Query 'PV Query: It was confirmed that the fall and hospitalization occurred on the same day, 25 Aug 2020. If correct, please update hospitalization date.' answered with 'data updated' (Site from Safety).	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:56:54
DataPoint Un-verified.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:56:50
User entered '25 Aug 2020' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 20:56:50
User opened query 'PV Query: It was confirmed that the fall and hospitalization occurred on the same day, 25 Aug 2020. If correct, please update hospitalization date.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 13:59:21
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 13:05:57
User entered '26 Aug 2020'	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:05:57
User entered '31 Aug 2020'	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:05:57
User entered 'No (N)'	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:05:57
User entered empty.	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Sep 2020 13:05:57
User entered '0'	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Sep 2020 13:05:57
User entered '0'	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Sep 2020 13:05:57
User entered '0'	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:05:57
User entered 'Not Related (NOT RELATED)'	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:35:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
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 19:30:28
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 17:04:17
DataPoint Un-verified.	Jennifer Torres (b) (4) (b) (4)	18 Nov 2020 17:03:46
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jennifer Torres (b) (4) (b) (4)	18 Nov 2020 17:03:46
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 08:09:19
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 13:05:57
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 16:32:15
User closed query 'PV Query: As the 1st dose of IP was administered on 04 Aug 2020, please clarify action taken with IP (none, withdrawn, dose delayed). If action taken with IP is to remain as not applicable please explain. ' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 20:13:06
Query 'PV Query: As the 1st dose of IP was administered on 04 Aug 2020, please clarify action taken with IP (none, withdrawn, dose delayed). If action taken with IP is to remain as not applicable please explain. ' answered with 'Dose was delayed-updated' (Site from Safety).	Mary Sergalis (b) (4)	18 Sep 2020 16:01:54
DataPoint Un-verified.	Mary Sergalis (b) (4)	18 Sep 2020 16:01:07
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	18 Sep 2020 16:01:07
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 13:05:57
User opened query 'PV Query: As the 1st dose of IP was administered on 04 Aug 2020, please clarify action taken with IP (none, withdrawn, dose delayed). If action taken with IP is to remain as not applicable please explain. ' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 22:41:00
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

None

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Sep 2020 13:05:57
User entered '0'	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:34:23
DataPoint Verified.	(b) (4)	22 Apr 2021 13:34:39
	(b) (4), (b) (6)	
User closed query 'According to eMR concomitant medication was given. Please review and update. Thanks. ' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 13:34:37
Query 'According to eMR concomitant medication was given. Please review and update. Thanks. ' answered with 'Data updated.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:51:44
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:50:47
Signature has been broken.	(b) (4), (b) (6)	16 Apr 2021 16:50:47
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 16:50:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:37:04
User opened query 'According to eMR concomitant medication was given. Please review and update. Thanks. ' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 15:37:02
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM #20 and 22 indication is LEFT HIP PAIN. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 16:45:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
	(b) (4)	
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM #20 and 22 indication is LEFT HIP PAIN. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' answered with 'updated' (Site from DM).	Mary Sergalis (b) (4)	17 Feb 2021 18:34:26
DataPoint Un-verified.	Mary Sergalis (b) (4)	17 Feb 2021 18:34:18
User entered '0' reason for change: Data Entry Error	Mary Sergalis (b) (4)	17 Feb 2021 18:34:18

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM #20 and 22 indication is LEFT HIP PAIN. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 06:19:09
DataPoint Un-verified.	Mary Sergalis (b) (4)	02 Nov 2020 14:52:16
User entered '1' reason for change: Data Entry Error	Mary Sergalis (b) (4)	02 Nov 2020 14:52:16
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 13:05:57
User entered '0'	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe (i.e. Surgical procedure and rehabilitation). Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 09:34:21
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe (i.e. Surgical procedure and rehabilitation). Please review and add a Con Procedure as appropriate or update action taken.' answered with 'Procedure added' (Site from DM).	Mary Sergalis (b) (4)	17 Oct 2020 18:24:05
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe (i.e. Surgical procedure and rehabilitation). Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 02:35:06
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 13:05:57
User entered 'I'	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4)	26 Oct 2020 16:32:23
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.	(b) (4), (b) (6)	20 Sep 2020 20:13:03
' (Site from Safety).		
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.	Mary Sergalis (b) (4)	18 Sep 2020 16:02:10
' answered with 'Event resolved' (Site from Safety).		
DataPoint Un-verified.	Mary Sergalis (b) (4)	18 Sep 2020 16:01:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Mary Sergalis (b) (4)	18 Sep 2020 16:01:07
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 13:05:57
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.	(b) (4), (b) (6)	10 Sep 2020 22:43:14
' (Site from Safety).		
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:05:57
User entered empty.	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Per updated statement in narrative "subject notified site of falling and fracturing left hip on 28 Aug 2020" - please confirm that this refers to the date that the subject contacted the site vs. the date the subject fell and fractured hip' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 18:20:56
Query 'PV Query: Per updated statement in narrative "subject notified site of falling and fracturing left hip on 28 Aug 2020" - please confirm that this refers to the date that the subject contacted the site vs. the date the subject fell and fractured hip' answered with 'that is correct- Subject did not contact site regarding the event until 28AUG2020' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 16:07:34
User opened query 'PV Query: Per updated statement in narrative "subject notified site of falling and fracturing left hip on 28 Aug 2020" - please confirm that this refers to the date that the subject contacted the site vs. the date the subject fell and fractured hip' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 15:56:33
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:34:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:35:57
User closed query 'According to eMR subject notified the site on 28Aug2020, please review and clarify. Thanks!' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 13:35:54
Query 'According to eMR subject notified the site on 28Aug2020, please review and clarify. Thanks!' answered with 'Data updated.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:52:12
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:50:47
Signature has been broken.	(b) (4), (b) (6)	16 Apr 2021 16:50:47

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT NOTIFIED THE SITE OF FALLING AND FRACTURING LEFT HIP ON THE 28-AUG-2020. PARTIAL HIP REPLACEMENT WAS PERFORMED ON 26-AUG-2020. SUBJECT DID NOT NOTIFY THE SITE UNTIL 29-AUG-2020 OF THE HOSPITALIZATION. SUBJECT HAS BEEN TRANSFERRED TO A REHABILITATION FACILITY ON 31-AUG-2020. MEDICAL RECORDS HAVE BEEN REQUESTED. SUBJECTS FIRST INJECTION OCCURRED ON 04-AUG-2020.' reason for change: Data Entry Error DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:50:47
	(b) (4), (b) (6)	16 Apr 2021 15:46:21
User opened query 'According to eMR subject notified the site on 28Aug2020, please review and clarify. Thanks!' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 15:46:17
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 17:35:41
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
	(b) (4)	
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'Discharge summary emailed. not relevant laboratory' (Site from Safety).	Mary Sergalis (b) (4)	17 Feb 2021 18:33:50

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 15:48:20
User closed query 'Per DM CLR: Narrative indicates that the subject ahd a Fractured RIGHT hip. However, AE indicates and LEFT HIP. Please reconcile and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 14:31:37
Query 'Per DM CLR: Narrative indicates that the subject ahd a Fractured RIGHT hip. However, AE indicates and LEFT HIP. Please reconcile and update accordingly. Otherwise, clarify.' answered with 'narrative corrected' (Site from DM).	Mary Sergalis (b) (4)	29 Jan 2021 14:00:27
DataPoint Un-verified.	Mary Sergalis (b) (4)	29 Jan 2021 14:00:11
User entered 'SUBJECT NOTIFIED THE SITE OF FALLING AND FRACTURING left HIP ON THE 25-AUG-2020. PARTIAL HIP REPLACEMENT WAS PERFORMED ON 26-AUG-2020. SUBJECT DID NOT NOTIFY THE SITE UNTIL 29-AUG-2020 OF THE HOSPITALIZATION. SUBJECT HAS BEEN TRANSFERRED TO A REHABILITATION FACILITY ON 31-AUG-2020. MEDICAL RECORDS HAVE BEEN REQUESTED. SUBJECTS FIRST INJECTION OCCURRED ON 04-AUG-2020.' reason for change: Data Entry Error	Mary Sergalis (b) (4)	29 Jan 2021 14:00:11
User opened query 'Per DM CLR: Narrative indicates that the subject ahd a Fractured RIGHT hip. However, AE indicates and LEFT HIP. Please reconcile and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 07:34:02

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = SUBJECT NOTIFIED THE SITE OF FALLING. Please review and determine if this should also be recorded as an Adverse Event (i.e., FALL). If yes, please record a medical condition and all applicable details in the AE eCRF.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 08:10:22
User closed query 'PV Query: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment medications were provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 19:41:51
User closed query 'PV Query: Please provide relevant laboratory tests and/or other relevant exams performed to diagnose, confirm, and/or monitor the event. ' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 19:41:49
User closed query 'PV Query: Was the fall witnessed? ' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 19:41:47
Query 'PV Query: Please provide relevant laboratory tests and/or other relevant exams performed to diagnose, confirm, and/or monitor the event. ' answered with 'No relevant lab test. X-ray added to procedures' (Site from Safety).	Mary Sergalis (b) (4)	19 Oct 2020 14:37:14
Query 'Per DM CLR: SAE Narrative = SUBJECT NOTIFIED THE SITE OF FALLING. Please review and determine if this should also be recorded as an Adverse Event (i.e., FALL). If yes, please record a medical condition and all applicable details in the AE eCRF.' answered with 'Fall added to AE' (Site from DM).	Mary Sergalis (b) (4)	19 Oct 2020 14:36:44
Query 'PV Query: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment medications were provided, please state so. ' answered with 'Known medications have been documented on concomitant medication page' (Site from Safety).	Mary Sergalis (b) (4)	19 Oct 2020 14:29:30
Query 'PV Query: Was the fall witnessed? ' answered with 'Unknown' (Site from Safety).	Mary Sergalis (b) (4)	17 Oct 2020 18:24:25

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = SUBJECT NOTIFIED THE SITE OF FALLING. Please review and determine if this should also be recorded as an Adverse Event (i.e., FALL). If yes, please record a medical condition and all applicable details in the AE eCRF.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 02:35:54
Query 'Per DM CLR: SAE Narrative = SUBJECT NOTIFIED THE SITE OF FALLING. Please review and determine if this should also be recorded as an Adverse Event. If yes, please record a medical condition and all applicable details in the AE eCRF.' canceled (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 02:35:50
User opened query 'Per DM CLR: SAE Narrative = SUBJECT NOTIFIED THE SITE OF FALLING. Please review and determine if this should also be recorded as an Adverse Event. If yes, please record a medical condition and all applicable details in the AE eCRF.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 02:35:22
User closed query 'PV Query: Please assess if the "Fall" met criteria for AE/SAE reporting. If so, please report. If not, please state so. ' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 20:12:59
User closed query 'PV Query: Please confirm that the fall occurred on 25 Aug 2020 as the subject was not hospitalized until the following day. ' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 20:12:57
User closed query 'PV Query: What was the reason for the fall? (i.e. accidental, dizziness, hypotension, poor eye vision, etc).' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 20:12:54
Query 'PV Query: What was the reason for the fall? (i.e. accidental, dizziness, hypotension, poor eye vision, etc).' answered with 'The fall was accidental' (Site from Safety).	Mary Sergalis (b) (4)	18 Sep 2020 16:03:37
Query 'PV Query: Please confirm that the fall occurred on 25 Aug 2020 as the subject was not hospitalized until the following day. ' answered with 'The fall occurred on the 25-Aug-2020 and the subject was hospitalized on that day' (Site from Safety).	Mary Sergalis (b) (4)	18 Sep 2020 16:03:25
Query 'PV Query: Please assess if the "Fall" met criteria for AE/SAE reporting. If so, please report. If not, please state so. ' answered with 'Fall does not meet criteria' (Site from Safety).	Mary Sergalis (b) (4)	18 Sep 2020 16:02:35

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 13:05:57
User opened query 'PV Query: What was the reason for the fall? (i.e. accidental, dizziness, hypotension, poor eye vision, etc).'	(b) (4), (b) (6)	10 Sep 2020 22:43:02
(Site from Safety).		
User opened query 'PV Query: Please confirm that the fall occurred on 25 Aug 2020 as the subject was not hospitalized until the following day. '	(b) (4), (b) (6)	10 Sep 2020 22:42:24
(Site from Safety).		
User opened query 'PV Query: Was the fall witnessed? '	(b) (4), (b) (6)	10 Sep 2020 22:42:11
(Site from Safety).		
User opened query 'PV Query: Please provide relevant laboratory tests and/or other relevant exams performed to diagnose, confirm, and/or monitor the event. '	(b) (4), (b) (6)	10 Sep 2020 22:42:00
(Site from Safety).		
User opened query 'PV Query: Please assess if the "Fall" met criteria for AE/SAE reporting. If so, please report. If not, please state so. '	(b) (4), (b) (6)	10 Sep 2020 22:41:45
(Site from Safety).		
User opened query 'PV Query: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment medications were provided, please state so. '	(b) (4), (b) (6)	10 Sep 2020 22:41:31
(Site from Safety).		
Query 'Per ETRTR: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.'	(b) (4), (b) (6)	06 Sep 2020 18:41:44
canceled (Site from CRA).		
Query 'Per ETRTR: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.'	(b) (4), (b) (6)	06 Sep 2020 18:41:42
canceled (Site from CRA).		

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per ETRTR: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from CRA).	(b) (4), (b) (6)	01 Sep 2020 19:49:04
User opened query 'Per ETRTR: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from CRA).	(b) (4), (b) (6)	01 Sep 2020 19:48:50
User entered 'Subject notified the site of falling and fracturing right hip on the 25-AUG-2020. Partial hip replacement was performed on 26-AUG-2020. Subject did not notify the site until 29-AUG-2020 of the hospitalization. Subject has been transferred to a Rehabilitation Facility on 31-AUG-2020. Medical records have been requested. Subjects first injection occurred on 04-AUG-2020.'	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

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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 'I'	System	31 Aug 2020 19:12:26

US3372005

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	06 Jan 2021 14:31:06
User entered '0'	System	31 Aug 2020 19:12:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:16:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	31 Aug 2020 19:12:26

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Fall, LLT: Fall - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 14:36:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 14:36:42
Data point term sent to Coder	System	19 Oct 2020 14:35:54
User entered 'Fall'	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'No (N)'	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

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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)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'No (N)'	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

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Folder: Adverse Events

Form: Adverse Events (2)

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '25 Aug 2020'	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:55

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered empty.	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

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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)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User entered empty.	System	19 Oct 2020 14:35:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'No (N)'	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

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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)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '25 Aug 2020'	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered empty.	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

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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)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User entered empty.	System	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'No (N)'	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '0'	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '0'	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '0'	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered empty.	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:55

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered empty.	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered empty.	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered empty.	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '0'	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '0'	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '0'	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 14:35:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 14:35:53
User entered 'Related (RELATED)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	19 Oct 2020 14:35:53
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 14:35:33
User entered empty.	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:32:35
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) (6)	18 Nov 2020 19:30:50
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 17:04:35
DataPoint Un-verified.	Jennifer Torres (b) (4) (b) (4)	18 Nov 2020 17:04:28
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jennifer Torres (b) (4) (b) (4)	18 Nov 2020 17:04:28
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 08:08:25
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:53:23
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 14:35:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 14:35:53
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	19 Oct 2020 14:35:53
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 14:35:33
User entered empty.	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:55

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
User closed query 'Per CDM: CCGs p. 33, Action taken with investigational product is expected to be "Not Applicable" if adverse event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:33:22
Query 'Per CDM: CCGs p. 33, Action taken with investigational product is expected to be "Not Applicable" if adverse event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate. ' answered with 'If you look it is marked "not applicable"' (Site from DM).	Mary Sergalis (b) (4)	08 Dec 2020 01:58:40
User opened query 'Per CDM: CCGs p. 33, Action taken with investigational product is expected to be "Not Applicable" if adverse event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 08:34:35
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:53:23
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 14:35:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 14:35:53
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	19 Oct 2020 14:35:53
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 14:35:33
User entered empty.	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:55

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '1' reason for change: Data Entry Error	Mary Sergalis (b) (4)	02 Nov 2020 14:53:03
User entered '0'	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '0'	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:53:23
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 14:38:29
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'updated' (Site from DM).	Mary Sergalis (b) (4)	02 Nov 2020 14:53:14
User entered '0' reason for change: Data Entry Error	Mary Sergalis (b) (4)	02 Nov 2020 14:53:03
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 04:21:22
User entered '1'	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:55

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:55

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered empty.	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered empty.	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User entered '0'	System	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52
User entered 'I'	System	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:25:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:47:07
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	08 Dec 2020 02:01:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Dec 2020 02:01:47
Data point term sent to Coder	System	08 Dec 2020 02:01:09
DataPoint Un-verified.	Mary Sergalis (b) (4)	08 Dec 2020 02:00:51
Coding entries removed.	Mary Sergalis (b) (4)	08 Dec 2020 02:00:51
User entered 'Intermittent CONSTIPATION' reason for change: Data Entry Error	Mary Sergalis (b) (4)	08 Dec 2020 02:00:51
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:53:23
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:46:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:46:40
Data point term sent to Coder	System	28 Oct 2020 17:57:13
User entered 'constipation'	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'No (N)'	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'No (N)'	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'No (N)'	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '28 Aug 2020'	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered empty.	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:34:29
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' answered with 'update- ae is continuing ' (Site from DM).	Mary Sergalis (b) (4)	08 Dec 2020 02:01:14
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 10:32:22
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered empty.	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered empty.	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'No (N)'	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

Death

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '0'	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '0'	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '0'	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered empty.	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered empty.	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered empty.	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered empty.	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '0'	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '0'	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '0'	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'Not Related (NOT RELATED)'	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 20:33:03
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.	(b) (4), (b) (6)	18 Nov 2020 19:31:20
' (Site from DM).		
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.	Jennifer Torres (b) (4)	18 Nov 2020 17:04:50
' answered with 'AE is not related to study procedure.'	(b) (4)	
(Site from DM).		
DataPoint Un-verified.	Jennifer Torres (b) (4)	18 Nov 2020 17:04:44
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jennifer Torres (b) (4)	18 Nov 2020 17:04:44
reason for change: Data Entry Error	(b) (4)	
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.	(b) (4), (b) (6)	18 Nov 2020 08:10:18
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
User closed query 'Per CDM: CCGs p. 33, Action taken with investigational product is expected to be "Not Applicable" if adverse event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:34:04
Query 'Per CDM: CCGs p. 33, Action taken with investigational product is expected to be "Not Applicable" if adverse event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate. ' answered with 'it is marked not applicable if you look' (Site from DM).	Mary Sergalis (b) (4)	08 Dec 2020 02:03:46
User opened query 'Per CDM: CCGs p. 33, Action taken with investigational product is expected to be "Not Applicable" if adverse event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 08:35:23
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

None

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '0'	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'I'	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '0'	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered empty.	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered empty.	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:16:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:47:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:47:11
Data point term sent to Coder	System	28 Oct 2020 18:03:22
User entered 'Gastroesophageal Reflux disease'	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'No (N)'	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'No (N)'	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'No (N)'	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '25 Aug 2020'	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered empty.	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User entered empty.	System	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'No (N)'	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '31 Aug 2020'	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered empty.	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User entered empty.	System	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'No (N)'	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '0'	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '0'	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '0'	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered empty.	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered empty.	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered empty.	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered empty.	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '0'	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '0'	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '0'	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'Not Related (NOT RELATED)'	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 20:33:20
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) (6)	18 Nov 2020 19:31:45
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 17:05:06
DataPoint Un-verified.	Jennifer Torres (b) (4) (b) (4)	18 Nov 2020 17:04:59
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jennifer Torres (b) (4) (b) (4)	18 Nov 2020 17:04:59
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 08:09:51
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
User closed query 'Per CDM: CCGs p. 33, Action taken with investigational product is expected to be "Not Applicable" if adverse event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:34:38
Query 'Per CDM: CCGs p. 33, Action taken with investigational product is expected to be "Not Applicable" if adverse event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate. ' answered with 'it is marked not applicable' (Site from DM).	Mary Sergalis (b) (4)	08 Dec 2020 02:01:47
User opened query 'Per CDM: CCGs p. 33, Action taken with investigational product is expected to be "Not Applicable" if adverse event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 08:35:47
Un-reviewed for Data Management.	(b) (4), (b) (6)	26 Nov 2020 08:35:42
Reviewed for Data Management.	(b) (4), (b) (6)	26 Nov 2020 08:35:39
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '0'	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'l'	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '0'	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered empty.	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered empty.	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User entered '0'	System	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47
User entered '0'	System	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:40:47

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
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)	07 Dec 2020 18:29:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Dec 2020 18:29:59
Data point term sent to Coder	System	07 Dec 2020 18:29:01
User entered 'insomnia'	Peter Jacob (b) (4)	07 Dec 2020 18:28:03
	(b) (4)	

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	07 Dec 2020 18:28:03

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	07 Dec 2020 18:28:03

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	07 Dec 2020 18:28:03

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	17 Feb 2021 18:35:38
User entered '28 Aug 2020' reason for change: Data Entry Error	System	17 Feb 2021 18:35:38
User closed query 'Per CDM: If start date is unknown, please confirm if start date was before or after the date of Informed consent and update accordingly.' (Site from DM).	Mary Sergalis (b) (4)	17 Feb 2021 18:35:38
Query 'Per CDM: If start date is unknown, please confirm if start date was before or after the date of Informed consent and update accordingly.' answered with 'the start date is entered. event started after signing consent' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 14:32:28
User opened query 'Per CDM: If start date is unknown, please confirm if start date was before or after the date of Informed consent and update accordingly.' (Site from DM).	Mary Sergalis (b) (4)	29 Jan 2021 14:02:24
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	08 Dec 2020 15:37:09
User entered 'un Aug 2020' (non-conformant).	System	07 Dec 2020 18:28:03
	Peter Jacob (b) (4)	07 Dec 2020 18:28:03

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	07 Dec 2020 18:28:03
	(b) (4)	

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 18:28:03

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
	(b) (4)	
User entered 'Yes (Y)'	Peter Jacob (b) (4)	07 Dec 2020 18:28:03
	(b) (4)	

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	07 Dec 2020 18:28:03
	(b) (4)	

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
User entered empty.	(b) (4) Peter Jacob (b) (4)	07 Dec 2020 18:28:03
	(b) (4)	

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 18:28:03

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Peter Jacob (b) (4)	07 Dec 2020 18:28:03

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	07 Dec 2020 18:28:03
	(b) (4)	

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
	(b) (4)	
User entered '0'	Peter Jacob (b) (4)	07 Dec 2020 18:28:03
	(b) (4)	

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
	(b) (4)	
User entered '0'	Peter Jacob (b) (4)	07 Dec 2020 18:28:03
	(b) (4)	

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
	(b) (4)	
User entered '0'	Peter Jacob (b) (4)	07 Dec 2020 18:28:03
	(b) (4)	

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	07 Dec 2020 18:28:03
	(b) (4)	

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	07 Dec 2020 18:28:03
	(b) (4)	

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
User entered empty.	(b) (4) Peter Jacob (b) (4)	07 Dec 2020 18:28:03
	(b) (4)	

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
User entered empty.	(b) (4) Peter Jacob (b) (4)	07 Dec 2020 18:28:03
	(b) (4)	

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
	(b) (4)	
User entered '0'	Peter Jacob (b) (4)	07 Dec 2020 18:28:03
	(b) (4)	

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	07 Dec 2020 18:28:03

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	07 Dec 2020 18:28:03

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
User entered 'Not Related (NOT RELATED)'	(b) (4) Peter Jacob (b) (4)	07 Dec 2020 18:28:03

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
User entered 'Not Related (NOT RELATED)'	(b) (4) Peter Jacob (b) (4)	07 Dec 2020 18:28:03

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Peter Jacob (b) (4)	07 Dec 2020 18:28:03

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

None

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
	(b) (4)	
User entered '0'	Peter Jacob (b) (4)	07 Dec 2020 18:28:03
	(b) (4)	

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
	(b) (4)	
User entered 'I'	Peter Jacob (b) (4)	07 Dec 2020 18:28:03
	(b) (4)	

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
	(b) (4)	
User entered '0'	Peter Jacob (b) (4)	07 Dec 2020 18:28:03
	(b) (4)	

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Peter Jacob (b) (4)	07 Dec 2020 18:28:03

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	07 Dec 2020 18:28:03

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 19:59:47
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	07 Dec 2020 18:28:03
	(b) (4)	

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Dec 2020 18:28:03

US3372005

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:16:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Dec 2020 18:28:03

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:16:55

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:05
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:36:30
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:56:03

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Oct 2020 18:58:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 18:58:48

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, COMBINATIONS, ATC: MULTIVITAMINS WITH MINERALS, PRODUCT: ASCORBIC ACID;BIOTIN;CALCIUM;CALCIUM PHOSPHATE DIBASIC;CHROMIC CHLORIDE;CUPRIC OXIDE;CYANOCOBALAMIN;FERROUS FUMARATE;FOLIC ACID;MAGNESIUM OXIDE;MANGANESE SULFATE;NICKEL SULFATE;NICOTINAMIDE;PANTOTHENIC ACID;PHYTOMENADIONE;POTASSIUM CHLORIDE;POTASSIUM IODIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SODIUM METASILICATE;SODIUM MOLYBDATE;SODIUM SELENATE;THIAMINE MONONITRATE;TOCOPHERYL ACETATE;VITAMIN D NOS;ZINC OXIDE, PRODUCTSYNONYM: CENTRUM SILVER [ASCORBIC ACID;BIOTIN;CALCIUM;CALCIUM PHOSPHATE DIBASIC;CHROMIC CHLORIDE;CUPRIC OXIDE;CYANOCOBALAMIN;FERROUS FUMARATE;FOLIC ACID;MAGNESIUM OXIDE;MANGANESE SULFATE;NICKEL SULFATE;NICOTINAMIDE;PANTOTHENIC ACID;PHYTOMENADIONE;POTASSIUM CHLORIDE;POTASSIUM IODIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SODIUM METASILICATE;SODIUM MOLYBDATE;SODIUM SELENATE;THIAMINE MONONITRATE;TOCOPHERYL ACETATE;VITAMIN D NOS;ZINC OXIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 17:30:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 17:30:47

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Aug 2020 20:59:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Aug 2020 20:59:02
Data point term sent to Coder	System	04 Aug 2020 20:58:09
User entered 'centrum silver'	Peter Jacob (b) (4)	04 Aug 2020 20:57:31

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:19:08
Query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' answered with 'This correct as entered' (Site from DM).	Mary Sergalis (b) (4)	20 Nov 2020 14:23:31
User opened query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 22:32:50
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:57:31

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered 'dietary supplement'	Peter Jacob (b) (4)	04 Aug 2020 20:57:31
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '1'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:57:31

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'tablet (TABLET)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:57:31

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 20:57:31
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:57:31

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 20:57:31
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:57:31

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:57:31

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Aug 2020 09:59:09
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'medication is ongoing' (Site from System).	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:57:45
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 20:57:31
User entered 'un UNK 1990'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:57:31

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered '0'	Peter Jacob (b) (4)	04 Aug 2020 20:57:31
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:57:31

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 20:57:31
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:57:31

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 20:57:31

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 20:57:31

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 20:57:31

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Aug 2020 20:47:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 20:47:07
Data point term sent to Coder	System	04 Aug 2020 20:59:10
User entered 'vitamin c'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:58:12

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:19:15
Query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' answered with 'This correct as entered' (Site from DM).	Mary Sergalis (b) (4)	20 Nov 2020 14:23:46
User opened query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 22:34:55
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:58:12

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'dietary supplement'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:58:12

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '1000'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:58:12
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered 'mg (mg)'	Peter Jacob (b) (4)	04 Aug 2020 20:58:12
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 20:58:12
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:58:12
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 20:58:12
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:58:12

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 20:58:12
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Aug 2020 09:59:14
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'medication is ongoing' (Site from System).	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:58:17
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 20:58:12
User entered 'un UNK 1990'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:58:12

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:58:12

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered 'Yes (Y)'	Peter Jacob (b) (4)	04 Aug 2020 20:58:12
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 20:58:12
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:58:12

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 20:58:12

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 20:58:12

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 20:58:12

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: B-COMPLEX [VITAMIN B COMPLEX] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Oct 2020 12:08:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:08:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: VITAMIN B-COMPLEX [VITAMIN B COMPLEX] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 11:16:58
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 Aug 2020 11:16:58
Data point term sent to Coder	System	04 Aug 2020 20:59:11
User entered 'vitamin B complex'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:59:01

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:19:20
Query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' answered with 'This correct as entered' (Site from DM).	Mary Sergalis (b) (4)	20 Nov 2020 14:24:02
User opened query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 22:35:37
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:59:01

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered 'dietary supplement'	Peter Jacob (b) (4)	04 Aug 2020 20:59:01
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '1'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:59:01
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered 'tablet (TABLET)'	Peter Jacob (b) (4)	04 Aug 2020 20:59:01
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 20:59:01
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered 'once daily (QD)'	Peter Jacob (b) (4)	04 Aug 2020 20:59:01
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 20:59:01
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:59:01

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 20:59:01
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Aug 2020 09:59:18
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'medication is ongoing' (Site from System).	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:59:05
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 20:59:01
User entered 'un UNK 1990'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:59:01

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered '0'	Peter Jacob (b) (4)	04 Aug 2020 20:59:01
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered 'Yes (Y)'	Peter Jacob (b) (4)	04 Aug 2020 20:59:01
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 20:59:01
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	04 Aug 2020 20:59:01
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 20:59:01

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 20:59:01

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 20:59:01

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Aug 2020 21:01:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 21:01:16
Data point term sent to Coder	System	04 Aug 2020 21:00:12
User entered 'vitamin D3'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:59:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:19:26
Query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' answered with 'This correct as entered' (Site from DM).	Mary Sergalis (b) (4)	20 Nov 2020 14:24:14
User opened query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 22:36:11
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:59:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'dietary supplement'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:59:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '2000'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:59:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'IU (IU)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:59:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 20:59:37
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:59:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:59:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:59:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:59:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Aug 2020 09:59:24
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'medication is ongoing' (Site from System).	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:59:52
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 20:59:37
User entered 'un UNK 1990'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:59:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:59:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:59:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 20:59:37
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 20:59:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 20:59:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 20:59:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 20:59:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Aug 2020 21:02:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 21:02:02
Data point term sent to Coder	System	04 Aug 2020 21:01:13
User entered 'calcium'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:00:26

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:19:29
Query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' answered with 'This correct as entered' (Site from DM).	Mary Sergalis (b) (4)	20 Nov 2020 14:24:24
User opened query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 22:36:42
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:00:26

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'dietary supplement'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:00:26

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '500'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:00:26
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:00:26

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 21:00:26
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:00:26

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 21:00:26
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:00:26

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:00:26

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Aug 2020 09:59:30
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'medication is ongoing' (Site from System).	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:00:30
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 21:00:26
User entered 'un UNK 1990'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:00:26

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:00:26

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:00:26

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 21:00:26
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:00:26

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:00:26

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:00:26

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 21:00:26

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Aug 2020 21:02:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 21:02:02
Data point term sent to Coder	System	04 Aug 2020 21:01:13
User entered 'magnesium'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:01:10

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:19:33
Query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' answered with 'This correct as entered' (Site from DM).	Mary Sergalis (b) (4)	20 Nov 2020 14:24:33
User opened query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 13:59:04
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:01:10

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'dietary supplement'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:01:10

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '420'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:01:10

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:01:10

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 21:01:10
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered 'once daily (QD)'	Peter Jacob (b) (4)	04 Aug 2020 21:01:10
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:01:10

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:01:10

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 21:01:10
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Aug 2020 09:59:34
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'medication is ongoing' (Site from System).	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:01:14
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 21:01:10
User entered 'un UNK 1990'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:01:10

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:01:10

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:01:10

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 21:01:10
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	04 Aug 2020 21:01:10
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:01:10

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:01:10

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 21:01:10

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: XANTOXYL, PRODUCTSYNONYM: LUTEIN [XANTOXYL] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Aug 2020 13:21:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 13:21:20
Data point term sent to Coder	System	04 Aug 2020 21:02:13
User entered 'lutein'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:01:56

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:19:37
Query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' answered with 'This correct as entered' (Site from DM).	Mary Sergalis (b) (4)	20 Nov 2020 14:24:43
User opened query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 13:59:15
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:01:56

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'dietary supplement'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:01:56

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '20'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:01:56

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:01:56

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:01:56

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:01:56

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 21:01:56
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:01:56

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:01:56

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Aug 2020 09:59:39
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'medication is ongoing' (Site from System).	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:02:00
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 21:01:56
User entered 'un UNK 1990'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:01:56

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:01:56

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:01:56

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:01:56

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:01:56

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:01:56

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:01:56

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 21:01:56

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, PRODUCT: LYCOPENE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 18:34:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 18:34:48
Data point term sent to Coder	System	26 Aug 2020 20:16:49
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	26 Aug 2020 20:16:48
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'please clarify what you are looking for since this is an ingredient found in multiple different fruits' (Site from System).	Peter Jacob (b) (4)	26 Aug 2020 20:16:48
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	17 Aug 2020 10:56:04
Data point term sent to Coder	System	04 Aug 2020 21:03:14
User entered 'lycopen'	Peter Jacob (b) (4)	04 Aug 2020 21:02:33

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:20:16
Query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' answered with 'This correct as entered' (Site from DM).	Mary Sergalis (b) (4)	20 Nov 2020 14:24:53
User opened query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 13:59:34
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:02:33

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'dietary supplement'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:02:33

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '30'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:02:33

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered 'mg (mg)'	Peter Jacob (b) (4)	04 Aug 2020 21:02:33
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:02:33

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:02:33

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 21:02:33
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:02:33

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 21:02:33
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Aug 2020 09:59:45
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'medication is ongoing' (Site from System).	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:02:37
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 21:02:33
User entered 'un UNK 1990'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:02:33

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:02:33

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:02:33

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 21:02:33
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:02:33

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:02:33

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:02:33

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 21:02:33

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: UBIDECARENONE, PRODUCTSYNONYM: COQ10 [UBIDECARENONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Aug 2020 22:20:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Aug 2020 22:20:10
Data point term sent to Coder	System	04 Aug 2020 21:03:14
User entered 'co q-10'	Peter Jacob (b) (4)	04 Aug 2020 21:03:06

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:20:21
Query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' answered with 'This correct as entered' (Site from DM).	Mary Sergalis (b) (4)	20 Nov 2020 14:25:03
User opened query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 13:59:42
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:03:06

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'dietary supplement'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:03:06

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '100'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:03:06

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:03:06

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:03:06

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:03:06
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:03:06

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:03:06

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:03:06

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Aug 2020 09:59:52
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'medication is ongoing' (Site from System).	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:03:11
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 21:03:06
User entered 'un UNK 1990'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:03:06

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered '0'	Peter Jacob (b) (4)	04 Aug 2020 21:03:06
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:03:06

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 21:03:06
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:03:06
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:03:06

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:03:06

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 21:03:06

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: MONASCUS PURPUREUS, PRODUCTSYNONYM: RED RICE YEAST - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Aug 2020 18:23:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:23:16
Data point term sent to Coder	System	04 Aug 2020 21:04:14
User entered 'red yeast rice'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:03:44

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:23:16
Query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' answered with 'This correct as entered' (Site from DM).	Mary Sergalis (b) (4)	20 Nov 2020 14:25:14
User opened query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 13:59:51
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:03:44

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'dietary supplement'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:03:44

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '600'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:03:44
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:03:44

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:03:44

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered 'twice daily (BID)'	Peter Jacob (b) (4)	04 Aug 2020 21:03:44
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 21:03:44
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:03:44

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:03:44
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Aug 2020 09:59:59
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'medication is ongoing' (Site from System).	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:03:50
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 21:03:44
User entered 'un UNK 1990'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:03:44

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:03:44

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:03:44

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:03:44

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:03:44

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Aug 2020 21:03:44

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:03:44

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 21:03:44

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: HERBAL DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, PRODUCT: LYCOPENE;PINUS SPP. BARK;PRUNUS AFRICANA BARK;SELENIUM AMINO ACID CHELATE;SERENOA REPENS FRUIT;SITOSTEROL;URTICA DIOICA LEAF;VITIS SPP.;ZINC, PRODUCTSYNONYM: PROSTATE COMPLEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 06:00:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 06:00:33
Data point term sent to Coder	System	04 Aug 2020 21:05:16
User entered 'prostate complex'	Peter Jacob (b) (4)	04 Aug 2020 21:04:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:23:28
Query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' answered with 'This correct as entered' (Site from DM).	Mary Sergalis (b) (4)	20 Nov 2020 14:25:27
User opened query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 13:59:59
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:04:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered 'dietary supplement'	Peter Jacob (b) (4)	04 Aug 2020 21:04:28
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '320'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:04:28
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered 'mg (mg)'	Peter Jacob (b) (4)	04 Aug 2020 21:04:28
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:04:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:04:28
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 21:04:28
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:04:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 21:04:28
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Aug 2020 10:00:06
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'medication is ongoing' (Site from System).	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:04:31
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 21:04:28
User entered 'un UNK 1990'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:04:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '0'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:04:28
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered 'Yes (Y)'	Peter Jacob (b) (4)	04 Aug 2020 21:04:28
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:04:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:04:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:04:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:04:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 21:04:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: KRILL OIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Sep 2020 13:50:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 13:50:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HERBAL CHOLESTEROL AND TRIGLYCERIDE REDUCERS, PRODUCT: KRILL OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 17:04:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 17:04:27
Data point term sent to Coder	System	04 Aug 2020 21:05:17
User entered 'krill oil'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:04:59

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:23:32
Query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' answered with 'This correct as entered' (Site from DM).	Mary Sergalis (b) (4)	20 Nov 2020 14:25:35
User opened query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:00:08
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:04:59

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'dietary supplement'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:04:59

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '500'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:04:59
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered 'mg (mg)'	Peter Jacob (b) (4)	04 Aug 2020 21:04:59
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 21:04:59
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:04:59

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:04:59

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:04:59

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:04:59

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Aug 2020 10:00:11
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'medication is ongoing' (Site from System).	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:05:03
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 21:04:59
User entered 'un UNK 1990'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:04:59

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:04:59

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:04:59

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:04:59

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:04:59

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:04:59

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:04:59

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 21:04:59

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIHEMORRHAGICS, ATC: VITAMIN K AND OTHER HEMOSTATICS, ATC: VITAMIN K, PRODUCT: VITAMIN K NOS, PRODUCTSYNONYM: VITAMIN K [VITAMIN K NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 12:15:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 12:15:24
Data point term sent to Coder	System	18 Sep 2020 16:20:47
User closed query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	System	18 Sep 2020 16:20:03
Query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' answered with 'Active ingredients added' (Site from System).	Mary Sergalis (b) (4)	18 Sep 2020 16:20:03
User entered 'SUPER K (Vitamin K: Vitamin K1, K2, MK-4 and MK-7)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	18 Sep 2020 16:19:46
User opened query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	09 Sep 2020 11:48:35
Data point term sent to Coder	System	04 Aug 2020 21:06:18
User entered 'super k 2'	Peter Jacob (b) (4)	04 Aug 2020 21:05:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:23:37
Query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' answered with 'This correct as entered' (Site from DM).	Mary Sergalis (b) (4)	20 Nov 2020 14:25:51
User opened query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:00:16
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:05:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered 'dietary supplement'	Peter Jacob (b) (4)	04 Aug 2020 21:05:37
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '260'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:05:37
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered 'ug (ug)'	Peter Jacob (b) (4)	04 Aug 2020 21:05:37
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 21:05:37
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:05:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 21:05:37
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:05:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:05:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Aug 2020 10:00:15
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'medication is ongoing' (Site from System).	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:05:41
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 21:05:37
User entered 'un UNK 1990'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:05:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered '0'	Peter Jacob (b) (4)	04 Aug 2020 21:05:37
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:05:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:05:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:05:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:05:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:05:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 21:05:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANABOLIC AGENTS FOR SYSTEMIC USE, ATC: ANABOLIC STEROIDS, ATC: ANDROSTAN DERIVATIVES, PRODUCT: PRASTERONE, PRODUCTSYNONYM: DHEA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Aug 2020 18:56:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 18:56:16
Data point term sent to Coder	System	04 Aug 2020 21:06:19
User entered 'DHEA'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:06:08

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:23:41
Query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' answered with 'This correct as entered' (Site from DM).	Mary Sergalis (b) (4)	20 Nov 2020 14:26:01
User opened query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:00:25
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:06:08

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'dietary supplement'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:06:08

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '25'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:06:08

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:06:08

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 21:06:08
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:06:08
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 21:06:08
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:06:08

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 21:06:08
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Aug 2020 10:00:21
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'medication is ongoing' (Site from System).	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:06:17
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 21:06:08
User entered 'un UNK 1990'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:06:08

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:06:08

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:06:08

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 21:06:08
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:06:08

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:06:08

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:06:08

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 21:06:08

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 20:48:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 20:48:59
Data point term sent to Coder	System	04 Aug 2020 21:07:22
User entered 'vitamin B-12'	Peter Jacob (b) (4)	04 Aug 2020 21:06:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:23:45
Query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' answered with 'This correct as entered' (Site from DM).	Mary Sergalis (b) (4)	20 Nov 2020 14:26:16
User opened query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:00:39
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:06:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered 'dietary supplement'	Peter Jacob (b) (4)	04 Aug 2020 21:06:53
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '1000'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:06:53
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:06:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 21:06:53
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:06:53
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:06:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:06:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:06:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Aug 2020 10:00:27
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'medication is ongoing' (Site from System).	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:06:58
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 21:06:53
User entered 'un UNK 1990'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:06:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:06:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:06:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:06:53
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:06:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:06:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:06:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 21:06:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CURCUMA LONGA, PRODUCTSYNONYM: TURMERIC [CURCUMA LONGA] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Nov 2020 01:25:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 01:25:48
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CURCUMA LONGA RHIZOME, PRODUCTSYNONYM: CURCUMIN TURMERIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 16:05:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 16:05:10
Data point term sent to Coder	System	04 Aug 2020 21:08:22
User entered 'turmeric curcumin'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:07:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:23:48
Query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' answered with 'This correct as entered' (Site from DM).	Mary Sergalis (b) (4)	20 Nov 2020 14:26:26
User opened query 'Per CDM: Prophylaxis is "No". Please confirm as indication is noted as "dietary supplement" and update if necessary. Thank you' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:00:47
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:07:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered 'dietary supplement'	Peter Jacob (b) (4)	04 Aug 2020 21:07:37
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered '1000'	Peter Jacob (b) (4)	04 Aug 2020 21:07:37
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:07:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 21:07:37
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:07:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:07:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:07:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:07:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Aug 2020 10:00:32
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'medication is ongoing' (Site from System).	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:07:49
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 21:07:37
User entered 'un UNK 1990'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:07:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:07:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered 'Yes (Y)'	Peter Jacob (b) (4)	04 Aug 2020 21:07:37
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	04 Aug 2020 21:07:37
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:07:37
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:07:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:07:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 21:07:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:05
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
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)	05 Aug 2020 00:26:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 00:26:01
Data point term sent to Coder	System	04 Aug 2020 21:09:25
User entered 'influenza vaccine'	Peter Jacob (b) (4)	04 Aug 2020 21:08:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:05
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:08:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:05
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'influenza prophylaxis/prevention'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:08:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:05
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '0.25'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:08:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:05
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'mL (mL)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:08:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:05
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:08:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:05
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'once (ONCE)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:08:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:05
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:08:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:05
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:08:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:05
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:08:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:05
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	16 Aug 2020 18:41:58
answered with 'per protocol all vaccines must be recorded' (Site from System).		
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Peter Jacob (b) (4)	04 Aug 2020 21:09:10
answered with 'per protocol all vaccines must be recorded' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 21:08:53
User entered 'un Nov 2019'	Peter Jacob (b) (4)	04 Aug 2020 21:08:53
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:05
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:08:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:05
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:08:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:05
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'un Nov 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:08:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:05
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:08:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:05
User entered empty.	System	04 Aug 2020 21:08:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:05
User entered empty.	System	04 Aug 2020 21:08:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:05
User entered empty.	System	04 Aug 2020 21:08:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:09
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Aug 2020 08:43:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 08:43:27
Data point term sent to Coder	System	04 Aug 2020 21:10:26
User entered 'pneumonia vaccine'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:10:11

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:09
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:10:11

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:09
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'pneumonia prophylaxis/prevention'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:10:11

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:09
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '0.5' reason for change: Data Entry Error	(b) (4) Mary Sergalis (b) (4)	18 Sep 2020 16:14:27
User entered '1'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:10:11

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:09
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4) Mary Sergalis (b) (4)	18 Sep 2020 16:14:27
User entered 'Other (OTHER)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:10:11

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:09
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'If dose unit is Other, Specify is given as 'ADMINISTRATION' which is unclear response ,Kindly review and verify if data entered 'ADMINISTRATION' is correct and consider to update data appropriately else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 05:34:24
Query 'If dose unit is Other, Specify is given as 'ADMINISTRATION' which is unclear response ,Kindly review and verify if data entered 'ADMINISTRATION' is correct and consider to update data appropriately else clarify.' answered with 'dose unit corrected' (Site from DM).	Mary Sergalis (b) (4)	18 Sep 2020 16:14:47
User entered empty; reason for change Data Entry Error	Mary Sergalis (b) (4)	18 Sep 2020 16:14:27
User opened query 'If dose unit is Other, Specify is given as 'ADMINISTRATION' which is unclear response ,Kindly review and verify if data entered 'ADMINISTRATION' is correct and consider to update data appropriately else clarify.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 07:30:53
User entered 'administration'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:10:11

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:09
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'once (ONCE)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:10:11

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:09
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:10:11

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:09
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:10:11

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:09
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:10:11

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:09
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	16 Aug 2020 18:42:02
answered with 'per protocol all vaccines must be recorded' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	Peter Jacob (b) (4)	04 Aug 2020 21:10:31
User entered 'un Nov 2019'	(b) (4)	
	System	04 Aug 2020 21:10:11
	Peter Jacob (b) (4)	04 Aug 2020 21:10:11
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:09
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:10:11

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:09
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:10:11

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:09
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'un Nov 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:10:11

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:09
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:10:11

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:09
User entered empty.	System	04 Aug 2020 21:10:11

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:09
User entered empty.	System	04 Aug 2020 21:10:11

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:09
User entered empty.	System	04 Aug 2020 21:10:11

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:16:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:16
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 15:58:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 15:58:28
Data point term sent to Coder	System	09 Oct 2020 15:57:43
Coding entries removed.	Peter Jacob (b) (4)	09 Oct 2020 15:57:29
Coding entries removed.	Peter Jacob (b) (4)	09 Oct 2020 15:57:29
User entered 'herpes zoster VACCINE' reason for change: Data Entry Error	Peter Jacob (b) (4)	09 Oct 2020 15:57:29
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 14:43:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 14:43:47
Data point term sent to Coder	System	04 Aug 2020 21:12:28
User entered 'shingles vaccine'	Peter Jacob (b) (4)	04 Aug 2020 21:11:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:16
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:11:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:16
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'herpes zoster PROPHYLAXIS/PREVENTION' reason for change:	(b) (4) Peter Jacob (b) (4)	09 Oct 2020 15:57:29
Data Entry Error		
User entered 'shingles prophylaxis/prevention'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:11:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:16
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '0.5' reason for change: Data Entry Error	(b) (4) Mary Sergalis (b) (4)	18 Sep 2020 16:15:35
User entered '1'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:11:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:16
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4) Mary Sergalis (b) (4)	18 Sep 2020 16:15:35
User entered 'Other (OTHER)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:11:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:16
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'If dose unit is Other, Specify is given as 'ADMINISTRATION' which is unclear response ,Kindly review and verify if data entered 'ADMINISTRATION' is correct and consider to update data appropriately else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 05:34:49
Query 'If dose unit is Other, Specify is given as 'ADMINISTRATION' which is unclear response ,Kindly review and verify if data entered 'ADMINISTRATION' is correct and consider to update data appropriately else clarify.' answered with 'dose unit updated' (Site from DM).	Mary Sergalis (b) (4)	18 Sep 2020 16:15:48
User entered empty; reason for change Data Entry Error	Mary Sergalis (b) (4)	18 Sep 2020 16:15:35
User opened query 'If dose unit is Other, Specify is given as 'ADMINISTRATION' which is unclear response ,Kindly review and verify if data entered 'ADMINISTRATION' is correct and consider to update data appropriately else clarify.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 07:31:35
User entered 'administration'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:11:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:16
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'once (ONCE)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:11:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:16
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:11:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:16
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:11:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:16
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:11:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:16
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	16 Aug 2020 18:42:05
answered with 'per protocol all vaccines must be recorded' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	Peter Jacob (b) (4)	04 Aug 2020 21:11:32
User entered 'un Nov 2019'	(b) (4)	
	System	04 Aug 2020 21:11:28
	Peter Jacob (b) (4)	04 Aug 2020 21:11:28
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:16:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:16
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	04 Aug 2020 21:11:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:16
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:11:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:16
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'un Nov 2019'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:11:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:16
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	04 Aug 2020 21:11:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:16
User entered empty.	System	04 Aug 2020 21:11:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:16
User entered empty.	System	04 Aug 2020 21:11:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:16
User entered empty.	System	04 Aug 2020 21:11:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:02:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:23:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:23:56
Data point term sent to Coder	System	18 Sep 2020 16:22:53
User entered 'Acetaminophen'	Mary Sergalis (b) (4) (b) (4) (b) (4)	18 Sep 2020 16:22:12

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:02:48
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Sep 2020 16:22:12

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:02:49
User entered 'Left Hip Pain'	Mary Sergalis (b) (4)	18 Sep 2020 16:22:12

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:02:51
User entered '325'	Mary Sergalis (b) (4) 	18 Sep 2020 16:22:12

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:02:54
User entered 'mg (mg)'	Mary Sergalis (b) (4)	18 Sep 2020 16:22:12

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:02:55
User entered empty.	Mary Sergalis (b) (4)	18 Sep 2020 16:22:12

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:02:56
User entered 'as needed (PRN)'	Mary Sergalis (b) (4)	18 Sep 2020 16:22:12

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:02:59
User entered empty.	Mary Sergalis (b) (4)	18 Sep 2020 16:22:12

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:01:32
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 16:22:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 16:22:22
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	18 Sep 2020 16:22:22
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 16:22:12
User entered empty.	Mary Sergalis (b) (4)	18 Sep 2020 16:22:12

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:01:30
User entered empty.	Mary Sergalis (b) (4)	18 Sep 2020 16:22:12

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:01:29
User entered '28 Aug 2020'	Mary Sergalis (b) (4)	18 Sep 2020 16:22:12

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:16:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:01:28
User entered '0'	Mary Sergalis (b) (4)	18 Sep 2020 16:22:12

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:01:26
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	18 Sep 2020 16:22:12

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:01:24
User entered empty.	Mary Sergalis (b) (4)	18 Sep 2020 16:22:12

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:01:22
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Sep 2020 16:22:12

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 16:22:12

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 16:22:12

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 16:22:12

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:04:04
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:27:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:27:56
Data point term sent to Coder	System	18 Sep 2020 16:27:08
User entered 'Bisacodyl'	Mary Sergalis (b) (4) 	18 Sep 2020 16:27:00

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:04:05
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Sep 2020 16:27:00

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:04:07
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 05:16:24
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'AE updated' (Site from DM).	Mary Sergalis (b) (4) (b) (4)	28 Oct 2020 17:57:33
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:10:01
User entered 'Constipation'	Mary Sergalis (b) (4)	18 Sep 2020 16:27:00

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:03:56
User entered '10'	Mary Sergalis (b) (4)	18 Sep 2020 16:27:00

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:03:58
User entered 'mg (mg)'	Mary Sergalis (b) (4)	18 Sep 2020 16:27:00

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:03:59
User entered empty.	Mary Sergalis (b) (4)	18 Sep 2020 16:27:00

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:04:01
User entered 'as needed (PRN)'	Mary Sergalis (b) (4)	18 Sep 2020 16:27:00

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:03:52
User entered empty.	Mary Sergalis (b) (4)	18 Sep 2020 16:27:00

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:03:50
User entered 'Oral (ORAL)'	Mary Sergalis (b) (4)	18 Sep 2020 16:27:00

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:03:49
User entered empty.	Mary Sergalis (b) (4)	18 Sep 2020 16:27:00

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:03:47
User entered '28 Aug 2020'	Mary Sergalis (b) (4)	18 Sep 2020 16:27:00

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:16:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:04:11
User entered '0'	Mary Sergalis (b) (4)	18 Sep 2020 16:27:00

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:04:13
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	18 Sep 2020 16:27:00

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:04:14
User entered empty.	Mary Sergalis (b) (4)	18 Sep 2020 16:27:00

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:04:16
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Sep 2020 16:27:00

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 16:27:00

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 16:27:00

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 16:27:00

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:16:55

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:04:55
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: ACETAMINOPHEN W/OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 20:07:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 20:07:38
Data point term sent to Coder	System	18 Sep 2020 16:29:10
User entered 'Acetaminophen/Oxycodone'	Mary Sergalis (b) (4) (b) (4) (b) (4)	18 Sep 2020 16:28:36

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:04:56
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Sep 2020 16:28:36

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:04:58
User entered 'Left Hip Pain'	Mary Sergalis (b) (4)	18 Sep 2020 16:28:36

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:04:59
User entered '5/325'	Mary Sergalis (b) (4)	18 Sep 2020 16:28:36

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:05:01
User entered 'mg (mg)'	Mary Sergalis (b) (4)	18 Sep 2020 16:28:36

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:05:03
User entered empty.	Mary Sergalis (b) (4)	18 Sep 2020 16:28:36

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:05:04
User entered 'as needed (PRN)'	Mary Sergalis (b) (4)	18 Sep 2020 16:28:36

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:05:07
User entered empty.	Mary Sergalis (b) (4)	18 Sep 2020 16:28:36

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:05:09
User entered 'Oral (ORAL)'	Mary Sergalis (b) (4)	18 Sep 2020 16:28:36

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:05:11
User entered empty.	Mary Sergalis (b) (4)	18 Sep 2020 16:28:36

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:05:12
User entered '25 Aug 2020'	Mary Sergalis (b) (4)	18 Sep 2020 16:28:36

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:16:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:05:14
User entered '0'	Mary Sergalis (b) (4)	18 Sep 2020 16:28:36

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:05:16
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	18 Sep 2020 16:28:36

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:05:17
User entered empty.	Mary Sergalis (b) (4)	18 Sep 2020 16:28:36

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:05:19
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Sep 2020 16:28:36

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 16:28:36

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 16:28:36

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 16:28:36

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:16:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:23
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:10:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:31:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:31:56
Data point term sent to Coder	System	18 Sep 2020 16:31:17
User entered 'Famotidine'	Mary Sergalis (b) (4) 	18 Sep 2020 16:30:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:23
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:10:58
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	18 Sep 2020 16:30:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:23
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:11:00
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 05:17:12
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'AE page updated' (Site from DM).	Mary Sergalis (b) (4)	28 Oct 2020 18:01:26
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:10:40
User entered 'Gastroesophageal Reflux Disease'	Mary Sergalis (b) (4)	18 Sep 2020 16:30:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:23
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:11:03
User entered '20'	Mary Sergalis (b) (4)	18 Sep 2020 16:30:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:23
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:11:04
User entered 'mg (mg)'	Mary Sergalis (b) (4)	18 Sep 2020 16:30:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:23
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:11:06
User entered empty.	Mary Sergalis (b) (4)	18 Sep 2020 16:30:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:23
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:11:07
User entered 'once daily (QD)'	Mary Sergalis (b) (4)	18 Sep 2020 16:30:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:23
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:11:09
User entered empty.	Mary Sergalis (b) (4)	18 Sep 2020 16:30:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:23
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:11:10
User entered 'Oral (ORAL)'	Mary Sergalis (b) (4)	18 Sep 2020 16:30:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:23
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:11:12
User entered empty.	Mary Sergalis (b) (4)	18 Sep 2020 16:30:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:23
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:11:13
User entered '25 Aug 2020'	Mary Sergalis (b) (4)	18 Sep 2020 16:30:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:16:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:23
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:11:15
User entered '0'	Mary Sergalis (b) (4)	18 Sep 2020 16:30:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:23
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:11:17
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Sep 2020 16:30:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:23
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:11:18
User entered '31 Aug 2020'	Mary Sergalis (b) (4)	18 Sep 2020 16:30:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:23
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:11:22
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Sep 2020 16:30:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:23
User entered '1'	System	18 Sep 2020 16:30:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:23
User entered '1'	System	18 Sep 2020 16:30:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:23
User entered '804 (804)'	System	18 Sep 2020 16:30:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:32
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:11:28
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 16:05:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 16:05:24
Data point term sent to Coder	System	09 Oct 2020 15:58:44
User entered 'rivaroxaban'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:58:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:32
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:12:08
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:58:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:32
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:12:10
User entered 'blood clot prevention'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:58:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:32
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:12:11
User entered '10'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:58:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:32
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:12:13
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:58:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:32
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:12:15
User entered empty.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:58:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:32
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:12:18
User entered 'once daily (QD)'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:58:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:16:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:32
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:12:19
User entered empty.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:58:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:32
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:12:21
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:58:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:32
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:12:23
User entered empty.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:58:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:32
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:12:24
User entered '28 Aug 2020'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:58:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:16:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:32
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:12:26
User entered '0'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:58:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:32
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:12:27
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:58:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:16:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:32
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:12:29
User entered '08 Sep 2020'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:58:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:32
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:12:30
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:58:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:32
User entered '1'	System	09 Oct 2020 15:58:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:32
User entered '1'	System	09 Oct 2020 15:58:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:13:32
User entered '804 (804)'	System	09 Oct 2020 15:58:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:16:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Oct 2020 15:59:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 15:59:31
Data point term sent to Coder	System	09 Oct 2020 15:58:44
User entered 'zolpidem'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:58:43

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:16:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:58:43

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:41
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'data updated' (Site from DM).	Mary Sergalis (b) (4)	07 Dec 2020 18:27:46
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 20:01:34
User entered 'insomnia'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:58:43

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:16:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '5'	(b) (4) Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:58:43

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:16:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered 'mg (mg)'	Peter Jacob (b) (4)	09 Oct 2020 15:58:43
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:16:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	09 Oct 2020 15:58:43
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:16:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	09 Oct 2020 15:58:43
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:16:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	09 Oct 2020 15:58:43
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:16:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:58:43

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:16:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	09 Oct 2020 15:58:43
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:16:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered '17 Sep 2020'	Peter Jacob (b) (4)	09 Oct 2020 15:58:43
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:16:55

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered '0'	Peter Jacob (b) (4)	09 Oct 2020 15:58:43
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:16:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered 'Yes (Y)'	Peter Jacob (b) (4)	09 Oct 2020 15:58:43
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:16:55

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	09 Oct 2020 15:58:43
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:16:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	09 Oct 2020 15:58:43

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:16:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 15:58:43

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 15:58:43

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:16:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Oct 2020 15:58:43

US3372005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:16:55

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:05
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:47:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	17 Oct 2020 18:22:03
User entered 'No (N)'	Peter Jacob (b) (4)	04 Aug 2020 21:11:42

US3372005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:16:55

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:46:38
User closed query 'Procedure Date is prior to ICF Date. Please verify and reconcile.' (Site from System).	System	17 Oct 2020 18:23:44
User entered '26 Aug 2020' reason for change: Data Entry Error	Mary Sergalis (b) (4)	17 Oct 2020 18:23:44
User opened query 'Procedure Date is prior to ICF Date. Please verify and reconcile.' (Site from System).	System	17 Oct 2020 18:23:28
User entered '26 Apr 2020'	Mary Sergalis (b) (4)	17 Oct 2020 18:23:28

US3372005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:16:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:46:38
User closed query 'Per CDM: According to a AE, right hip was fractured, however here it is entered as "Left". Please review both and make necessary updates. Thank you!' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 05:29:54
Query 'Per CDM: According to a AE, right hip was fractured, however here it is entered as "Left". Please review both and make necessary updates. Thank you!' answered with 'Updated to Left hip' (Site from DM).	Mary Sergalis (b) (4)	19 Oct 2020 14:37:47
User opened query 'Per CDM: According to a AE, right hip was fractured, however here it is entered as "Left". Please review both and make necessary updates. Thank you!' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:34:13
User entered 'Left Hip Hemiarthroplasty'	Mary Sergalis (b) (4)	17 Oct 2020 18:23:28

US3372005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:46:38
User entered 'Adverse Event (AE)'	Mary Sergalis (b) (4) 	17 Oct 2020 18:23:28

US3372005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:16:55

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:46:38
User entered empty.	Mary Sergalis (b) (4)	17 Oct 2020 18:23:28

US3372005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:16:55

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:58:32
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:46:38
User entered '25 Aug 2020'	Mary Sergalis (b) (4)	19 Oct 2020 14:38:22

US3372005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:16:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:58:32
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:46:38
User entered 'Left Hip X-ray'	Mary Sergalis (b) (4)	19 Oct 2020 14:38:22

US3372005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:16:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:58:32
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:46:38
User entered 'Adverse Event (AE)'	Mary Sergalis (b) (4)	19 Oct 2020 14:38:22

US3372005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:16:55

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:58:32
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:46:38
User entered empty.	Mary Sergalis (b) (4)	19 Oct 2020 14:38:22

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'USA-US056-2020-MRNA-1273-P301000001'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'Yes (Y)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'Yes (Y)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'Mira'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'Baron'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered '2277 Palm beach Lakes Blvd'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'West Palm Beach'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered empty.	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered '33409'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 20:13:55
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:11:05
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
User entered 'US' (non-conformant).	System	31 Aug 2020 20:13:40

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	19 Apr 2021 13:16:24
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:10:30
	(b) (4)	
Signature has been broken.	System	18 Feb 2021 17:36:55
User entered '10'	System	18 Feb 2021 17:36:55
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered '9'	System	01 Feb 2021 15:45:34
User entered '8'	System	06 Jan 2021 19:14:12
User entered '7'	System	19 Nov 2020 17:03:34
User entered '6'	System	03 Nov 2020 12:59:15
User entered '5'	System	20 Oct 2020 12:00:15
User entered '4'	System	19 Oct 2020 19:42:05
User entered '3'	System	12 Oct 2020 14:30:57
User entered '2'	System	20 Sep 2020 20:14:05
User entered '1'	System	31 Aug 2020 20:13:40

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'USA-US056-2020-MRNA-1273-P301000001'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'Yes (Y)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'Yes (Y)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'Mira'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'Baron'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered '2277 Palm beach Lakes Blvd'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'West Palm Beach'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered empty.	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered '33409'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 20:13:55
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:11:05
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
User entered 'US' (non-conformant).	System	31 Aug 2020 20:13:40

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	19 Apr 2021 13:16:24
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:10:30
	(b) (4)	
Signature has been broken.	System	18 Feb 2021 17:36:55
User entered '10'	System	18 Feb 2021 17:36:55
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered '9'	System	01 Feb 2021 15:45:34
User entered '8'	System	06 Jan 2021 19:14:12
User entered '7'	System	19 Nov 2020 17:03:34
User entered '6'	System	03 Nov 2020 12:59:15
User entered '5'	System	20 Oct 2020 12:00:15
User entered '4'	System	19 Oct 2020 19:42:05
User entered '3'	System	12 Oct 2020 14:30:57
User entered '2'	System	20 Sep 2020 20:14:05
User entered '1'	System	31 Aug 2020 20:13:40

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:16:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
User entered '31/Aug/2020 16:13'	System	31 Aug 2020 20:13:40

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:16:55

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.

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
User entered 'I'	(b) (4), (b) (6)	31 Aug 2020 20:13:40

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'USA-US056-2020-MRNA-1273-P301000001'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'Yes (Y)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'Yes (Y)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'Mira'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'Baron'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered '2277 Palm beach Lakes Blvd'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'West Palm Beach'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered empty.	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered '33409'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 20:13:55
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:11:05
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
User entered 'US' (non-conformant).	System	31 Aug 2020 20:13:40

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	19 Apr 2021 13:16:24
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:10:30
	(b) (4)	
Signature has been broken.	System	18 Feb 2021 17:36:55
User entered '10'	System	18 Feb 2021 17:36:55
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered '9'	System	01 Feb 2021 15:45:34
User entered '8'	System	06 Jan 2021 19:14:12
User entered '7'	System	19 Nov 2020 17:03:34
User entered '6'	System	03 Nov 2020 12:59:15
User entered '5'	System	20 Oct 2020 12:00:15
User entered '4'	System	19 Oct 2020 19:42:05
User entered '3'	System	12 Oct 2020 14:30:57
User entered '2'	System	20 Sep 2020 20:14:05
User entered '1'	System	31 Aug 2020 20:13:40

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:16:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:05:49
User entered '20/Sep/2020 16:14'	System	20 Sep 2020 20:14:05

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:16:55

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.

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:05:51
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:30:47
User entered 'I'	(b) (4), (b) (6)	20 Sep 2020 20:14:05

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'USA-US056-2020-MRNA-1273-P301000001'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'Yes (Y)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'Yes (Y)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'Mira'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'Baron'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered '2277 Palm beach Lakes Blvd'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'West Palm Beach'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered empty.	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered '33409'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 20:13:55
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:11:05
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
User entered 'US' (non-conformant).	System	31 Aug 2020 20:13:40

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	19 Apr 2021 13:16:24
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:10:30
	(b) (4)	
Signature has been broken.	System	18 Feb 2021 17:36:55
User entered '10'	System	18 Feb 2021 17:36:55
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered '9'	System	01 Feb 2021 15:45:34
User entered '8'	System	06 Jan 2021 19:14:12
User entered '7'	System	19 Nov 2020 17:03:34
User entered '6'	System	03 Nov 2020 12:59:15
User entered '5'	System	20 Oct 2020 12:00:15
User entered '4'	System	19 Oct 2020 19:42:05
User entered '3'	System	12 Oct 2020 14:30:57
User entered '2'	System	20 Sep 2020 20:14:05
User entered '1'	System	31 Aug 2020 20:13:40

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:16:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:06:04
User entered '12/Oct/2020 14:30'	System	12 Oct 2020 14:30:57

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:16:55

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.

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:06:06
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 19:41:59
User entered 'I'	(b) (4), (b) (6)	12 Oct 2020 14:30:57

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'USA-US056-2020-MRNA-1273-P301000001'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'Yes (Y)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'Yes (Y)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'Mira'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'Baron'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered '2277 Palm beach Lakes Blvd'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'West Palm Beach'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered empty.	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered '33409'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 20:13:55
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:11:05
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
User entered 'US' (non-conformant).	System	31 Aug 2020 20:13:40

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	19 Apr 2021 13:16:24
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:10:30
	(b) (4)	
Signature has been broken.	System	18 Feb 2021 17:36:55
User entered '10'	System	18 Feb 2021 17:36:55
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered '9'	System	01 Feb 2021 15:45:34
User entered '8'	System	06 Jan 2021 19:14:12
User entered '7'	System	19 Nov 2020 17:03:34
User entered '6'	System	03 Nov 2020 12:59:15
User entered '5'	System	20 Oct 2020 12:00:15
User entered '4'	System	19 Oct 2020 19:42:05
User entered '3'	System	12 Oct 2020 14:30:57
User entered '2'	System	20 Sep 2020 20:14:05
User entered '1'	System	31 Aug 2020 20:13:40

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:16:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 19:06:15
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 18:51:46
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:46:03
User entered '19/Oct/2020 15:42'	System	19 Oct 2020 19:42:05

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:16:55

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.

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 19:06:16
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 18:51:46
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:46:03
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 11:59:58
User entered 'I'	(b) (4), (b) (6)	19 Oct 2020 19:42:05

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'USA-US056-2020-MRNA-1273-P301000001'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'Yes (Y)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'Yes (Y)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'Mira'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'Baron'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered '2277 Palm beach Lakes Blvd'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'West Palm Beach'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered empty.	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered '33409'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 20:13:55
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:11:05
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
User entered 'US' (non-conformant).	System	31 Aug 2020 20:13:40

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	19 Apr 2021 13:16:24
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:10:30
	(b) (4)	
Signature has been broken.	System	18 Feb 2021 17:36:55
User entered '10'	System	18 Feb 2021 17:36:55
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered '9'	System	01 Feb 2021 15:45:34
User entered '8'	System	06 Jan 2021 19:14:12
User entered '7'	System	19 Nov 2020 17:03:34
User entered '6'	System	03 Nov 2020 12:59:15
User entered '5'	System	20 Oct 2020 12:00:15
User entered '4'	System	19 Oct 2020 19:42:05
User entered '3'	System	12 Oct 2020 14:30:57
User entered '2'	System	20 Sep 2020 20:14:05
User entered '1'	System	31 Aug 2020 20:13:40

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:16:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:06:26
User entered '20/Oct/2020 12:00'	System	20 Oct 2020 12:00:15

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:16:55

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.

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:06:28
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 12:59:08
User entered 'I'	(b) (4), (b) (6)	20 Oct 2020 12:00:15

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'USA-US056-2020-MRNA-1273-P301000001'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'Yes (Y)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'Yes (Y)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'Mira'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'Baron'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered '2277 Palm beach Lakes Blvd'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'West Palm Beach'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered empty.	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered '33409'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 20:13:55
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:11:05
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
User entered 'US' (non-conformant).	System	31 Aug 2020 20:13:40

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	19 Apr 2021 13:16:24
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:10:30
	(b) (4)	
Signature has been broken.	System	18 Feb 2021 17:36:55
User entered '10'	System	18 Feb 2021 17:36:55
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered '9'	System	01 Feb 2021 15:45:34
User entered '8'	System	06 Jan 2021 19:14:12
User entered '7'	System	19 Nov 2020 17:03:34
User entered '6'	System	03 Nov 2020 12:59:15
User entered '5'	System	20 Oct 2020 12:00:15
User entered '4'	System	19 Oct 2020 19:42:05
User entered '3'	System	12 Oct 2020 14:30:57
User entered '2'	System	20 Sep 2020 20:14:05
User entered '1'	System	31 Aug 2020 20:13:40

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:16:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:06:37
User entered '03/Nov/2020 07:59'	System	03 Nov 2020 12:59:15

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:16:55

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.

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:03:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:06:39
User entered 'I'	(b) (4), (b) (6)	03 Nov 2020 12:59:15

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'USA-US056-2020-MRNA-1273-P301000001'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'Yes (Y)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'Yes (Y)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'Mira'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'Baron'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered '2277 Palm beach Lakes Blvd'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'West Palm Beach'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered empty.	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered '33409'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 20:13:55
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:11:05
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
User entered 'US' (non-conformant).	System	31 Aug 2020 20:13:40

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	19 Apr 2021 13:16:24
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:10:30
	(b) (4)	
Signature has been broken.	System	18 Feb 2021 17:36:55
User entered '10'	System	18 Feb 2021 17:36:55
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered '9'	System	01 Feb 2021 15:45:34
User entered '8'	System	06 Jan 2021 19:14:12
User entered '7'	System	19 Nov 2020 17:03:34
User entered '6'	System	03 Nov 2020 12:59:15
User entered '5'	System	20 Oct 2020 12:00:15
User entered '4'	System	19 Oct 2020 19:42:05
User entered '3'	System	12 Oct 2020 14:30:57
User entered '2'	System	20 Sep 2020 20:14:05
User entered '1'	System	31 Aug 2020 20:13:40

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:16:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 20:38:16
User entered '19/Nov/2020 17:03'	System	19 Nov 2020 17:03:34

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:16:55

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.

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:14:03
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:38:17
User entered 'I'	(b) (4), (b) (6)	19 Nov 2020 17:03:34

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'USA-US056-2020-MRNA-1273-P301000001'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'Yes (Y)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'Yes (Y)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'Mira'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'Baron'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered '2277 Palm beach Lakes Blvd'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'West Palm Beach'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered empty.	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered '33409'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 20:13:55
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:11:05
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
User entered 'US' (non-conformant).	System	31 Aug 2020 20:13:40

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	19 Apr 2021 13:16:24
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:10:30
	(b) (4)	
Signature has been broken.	System	18 Feb 2021 17:36:55
User entered '10'	System	18 Feb 2021 17:36:55
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered '9'	System	01 Feb 2021 15:45:34
User entered '8'	System	06 Jan 2021 19:14:12
User entered '7'	System	19 Nov 2020 17:03:34
User entered '6'	System	03 Nov 2020 12:59:15
User entered '5'	System	20 Oct 2020 12:00:15
User entered '4'	System	19 Oct 2020 19:42:05
User entered '3'	System	12 Oct 2020 14:30:57
User entered '2'	System	20 Sep 2020 20:14:05
User entered '1'	System	31 Aug 2020 20:13:40

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:16:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:47:34
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '06/Jan/2021 14:14'	(b) (4) System	06 Jan 2021 19:14:12

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:16:55

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:47:34
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:45:22
User entered 'I'	(b) (4), (b) (6)	06 Jan 2021 19:14:12

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'USA-US056-2020-MRNA-1273-P301000001'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'Yes (Y)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'Yes (Y)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'Mira'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'Baron'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered '2277 Palm beach Lakes Blvd'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'West Palm Beach'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered empty.	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered '33409'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 20:13:55
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:11:05
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
User entered 'US' (non-conformant).	System	31 Aug 2020 20:13:40

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	19 Apr 2021 13:16:24
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:10:30
	(b) (4)	
Signature has been broken.	System	18 Feb 2021 17:36:55
User entered '10'	System	18 Feb 2021 17:36:55
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered '9'	System	01 Feb 2021 15:45:34
User entered '8'	System	06 Jan 2021 19:14:12
User entered '7'	System	19 Nov 2020 17:03:34
User entered '6'	System	03 Nov 2020 12:59:15
User entered '5'	System	20 Oct 2020 12:00:15
User entered '4'	System	19 Oct 2020 19:42:05
User entered '3'	System	12 Oct 2020 14:30:57
User entered '2'	System	20 Sep 2020 20:14:05
User entered '1'	System	31 Aug 2020 20:13:40

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 17:16:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:47:34
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered '01/Feb/2021 15:45'	(b) (4) System	01 Feb 2021 15:45:34

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 17:16:55

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:47:34
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 17:35:54
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
User entered 'I'	(b) (4), (b) (6)	01 Feb 2021 15:45:34

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'USA-US056-2020-MRNA-1273-P301000001'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'Yes (Y)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'Yes (Y)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'Mira'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'Baron'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered '2277 Palm beach Lakes Blvd'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'West Palm Beach'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered empty.	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered '33409'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 20:13:55
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:11:05
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
User entered 'US' (non-conformant).	System	31 Aug 2020 20:13:40

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	19 Apr 2021 13:16:24
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:10:30
	(b) (4)	
Signature has been broken.	System	18 Feb 2021 17:36:55
User entered '10'	System	18 Feb 2021 17:36:55
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered '9'	System	01 Feb 2021 15:45:34
User entered '8'	System	06 Jan 2021 19:14:12
User entered '7'	System	19 Nov 2020 17:03:34
User entered '6'	System	03 Nov 2020 12:59:15
User entered '5'	System	20 Oct 2020 12:00:15
User entered '4'	System	19 Oct 2020 19:42:05
User entered '3'	System	12 Oct 2020 14:30:57
User entered '2'	System	20 Sep 2020 20:14:05
User entered '1'	System	31 Aug 2020 20:13:40

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 17:16:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:47:34
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:10:30
User entered '18/Feb/2021 12:36'	(b) (4) System	18 Feb 2021 17:36:55

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 17:16:55

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:47:34
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:10:30
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:55

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'USA-US056-2020-MRNA-1273-P301000001'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'Yes (Y)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'Yes (Y)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered 'No (N)'	System	31 Aug 2020 20:12:45

US3372005

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'Mira'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'Baron'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

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Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered '2277 Palm beach Lakes Blvd'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

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Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered 'West Palm Beach'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

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Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered empty.	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:55

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:41:42
Amendment Manager: User entered '33409'	System	14 Sep 2020 21:41:42
Reviewed for Safety.	(b) (4), (b) (6)	31 Aug 2020 20:13:32
User entered (b) (6)	System	31 Aug 2020 20:12:45

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 20:13:55
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:11:05
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
User entered 'US' (non-conformant).	System	31 Aug 2020 20:13:40

US3372005

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	19 Apr 2021 13:16:24
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:10:30
	(b) (4)	
Signature has been broken.	System	18 Feb 2021 17:36:55
User entered '10'	System	18 Feb 2021 17:36:55
User signature succeeded.	Mira Baron (b) (4)	12 Feb 2021 17:31:03
	(b) (4)	
User entered '9'	System	01 Feb 2021 15:45:34
User entered '8'	System	06 Jan 2021 19:14:12
User entered '7'	System	19 Nov 2020 17:03:34
User entered '6'	System	03 Nov 2020 12:59:15
User entered '5'	System	20 Oct 2020 12:00:15
User entered '4'	System	19 Oct 2020 19:42:05
User entered '3'	System	12 Oct 2020 14:30:57
User entered '2'	System	20 Sep 2020 20:14:05
User entered '1'	System	31 Aug 2020 20:13:40

US3372005

Folder: SAE USA-US056-2020-MRNA-1273-P301000001

Form: Safety Report Form (11)

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[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:36:15
User signature succeeded.	Mira Baron (b) (4)	19 Apr 2021 19:06:23
User entered '19/Apr/2021 06:16'	(b) (4) System	19 Apr 2021 13:16:24

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Form: Safety Report Form (11)

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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)	22 Apr 2021 13:36:15
User signature succeeded.	Mira Baron (b) (4)	19 Apr 2021 19:06:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:16:24