

US3372005 (Prod: Palm Beach Research Center)

Generated By: (b) (6)

Generated On: 26 Nov 2020 11:01:16

All time stamps listed in this document are displayed in GMT

US3372005

Form: Participant Creation

Generated On: 26 Nov 2020 11:01:16

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:16

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	31 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:16

Date of Birth (MMM yyyy)	(b) (6) 1925
Age	94
Age Units	YEARS
Age (Derived)	94
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:16

Date of Informed Consent (<i>dd MMM yyyy</i>)	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

Generated On: 26 Nov 2020 11:01:16

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:01:16

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:16

Condition	INGUINAL HERNIA - LEFT
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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 (2)

Generated On: 26 Nov 2020 11:01:16

Condition	OSTEOARTHRITIS LEFT KNEE
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:16

Condition	LEFT KNEE REPLACEMENT
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 11:01:16

Condition	OSTEOARTHRITIS RIGHT KNEE
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 11:01:16

Condition	RIGHT KNEE REPLACEMENT
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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 (6)

Generated On: 26 Nov 2020 11:01:16

Condition	INGUINAL HERNIA - RIGHT
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 11:01:16

Condition	LEFT INGUINAL HERNIORRHAPHY
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 11:01:16

Condition	RIGHT INGUINAL HERNIORRHAPHY
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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

Generated On: 26 Nov 2020 11:01:16

Were vital signs assessed?	Yes ☒
	No ☐
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>)	133.2 kg
BMI (<i>xxx.x</i>)	50.38058 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	36.1 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
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

Generated On: 26 Nov 2020 11:01:16

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

Generated On: 26 Nov 2020 11:01:16

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

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:16

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

Generated On: 26 Nov 2020 11:01:16

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	04 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:16

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

Generated On: 26 Nov 2020 11:01:16

Height	162.6 cm
Weight	61.2 kg

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:16

Height	162.6 cm
Weight	61.2 kg
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
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 ☒ Axillary ☐ Other ☐
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)

Generated On: 26 Nov 2020 11:01:16

Height	162.6 cm
Weight	61.2 kg
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
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 ☒ Axillary ☐ Other ☐
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

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:16

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

Generated On: 26 Nov 2020 11:01:16

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

Generated On: 26 Nov 2020 11:01:16

Was the sample collected?

Yes ☒

No ☐

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

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:01:16

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

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:16

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

Yes ☐	
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: 26 Nov 2020 11:01:16

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 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:16

Yes ☐	
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: 26 Nov 2020 11:01:16

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 ☒

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:16

Yes ☐	
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: 26 Nov 2020 11:01:16

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 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:16

Yes ☐	
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: 26 Nov 2020 11:01:16

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 ☒

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:16

Yes ☐	
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: 26 Nov 2020 11:01:16

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 ☒

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:16

Yes ☐	
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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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

Generated On: 26 Nov 2020 11:01:16

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

Generated On: 26 Nov 2020 11:01:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372005

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

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

Generated On: 26 Nov 2020 11:01:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372005

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

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

Generated On: 26 Nov 2020 11:01:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372005

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:16

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	15 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:16

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
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 ☒
	Axillary ☐
	Other ☐
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)

Generated On: 26 Nov 2020 11:01:16

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
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 ☒
	Axillary ☐
	Other ☐
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

Generated On: 26 Nov 2020 11:01:16

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

Generated On: 26 Nov 2020 11:01:16

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

Generated On: 26 Nov 2020 11:01:16

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	15 SEP 2020
Collection time (<i>00:00-23:59</i>)	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

Generated On: 26 Nov 2020 11:01:16

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

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

Yes ☐	
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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

Yes ☐	
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: 26 Nov 2020 11:01:16

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 ☒

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:16

Yes ☐	
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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

Yes ☐	
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: 26 Nov 2020 11:01:16

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 ☒

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:16

Yes ☐	
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: 26 Nov 2020 11:01:16

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 ☒

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:16

Yes ☐	
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

Generated On: 26 Nov 2020 11:01:16

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

Generated On: 26 Nov 2020 11:01:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372005

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

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

Generated On: 26 Nov 2020 11:01:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372005

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

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

Generated On: 26 Nov 2020 11:01:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372005

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:16

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	29 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

Were vital signs assessed?	Yes ☐
	No ☒
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3372005

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:16

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

Generated On: 26 Nov 2020 11:01:16

Was the sample collected?

Yes ☒

No ☐

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

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:01:16

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

[Patient Cloud Close Date & Time](#)

05 OCT 2020 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2020 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2020 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2020 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:16

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

[Patient Cloud Close Date & Time](#)

02 NOV 2020 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2020 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT

DAY 103

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2020 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:16

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:01:16

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have 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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 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: 26 Nov 2020 11:01:16

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:16

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:01:16

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 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: 26 Nov 2020 11:01:16

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:16

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:01:16

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 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: 26 Nov 2020 11:01:16

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 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: 26 Nov 2020 11:01:16

TIMEPOINT

DAY 166

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 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: 26 Nov 2020 11:01:16

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 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: 26 Nov 2020 11:01:16

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 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: 26 Nov 2020 11:01:16

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 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: 26 Nov 2020 11:01:16

TIMEPOINT

DAY 194

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 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: 26 Nov 2020 11:01:16

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 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: 26 Nov 2020 11:01:16

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 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: 26 Nov 2020 11:01:16

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 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: 26 Nov 2020 11:01:16

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 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: 26 Nov 2020 11:01:16

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 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: 26 Nov 2020 11:01:16

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 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: 26 Nov 2020 11:01:16

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:16

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:01:16

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 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: 26 Nov 2020 11:01:16

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 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: 26 Nov 2020 11:01:16

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 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: 26 Nov 2020 11:01:16

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT

DAY 425

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

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

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

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

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

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

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

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31 JAN 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

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07 FEB 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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14 FEB 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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

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17 FEB 2022 00:01

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21 FEB 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

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28 FEB 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

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07 MAR 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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10 MAR 2022 00:01

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14 MAR 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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17 MAR 2022 00:01

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21 MAR 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:01:16

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

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28 MAR 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

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04 APR 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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21 APR 2022 00:01

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25 APR 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

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16 MAY 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

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30 MAY 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT

DAY 670

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

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

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

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

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

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

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: 26 Nov 2020 11:01:16

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

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06 JUN 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

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13 JUN 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

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20 JUN 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT

DAY 691

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

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

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

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

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

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

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

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27 JUN 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT

DAY 698

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

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

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

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

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

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

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

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04 JUL 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

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11 JUL 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

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18 JUL 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

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25 JUL 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:01:16

TIMEPOINT

DAY 796

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

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

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

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

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

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

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: 26 Nov 2020 11:01:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3372005

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

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

Generated On: 26 Nov 2020 11:01:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372005

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

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 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:16

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3372005

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:01:16

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☐

US3372005

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:01:16

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3372005

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:01:16

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)

Generated On: 26 Nov 2020 11:01:16

AEID	USA-US056-2020-MRNA-1273-P30 1000001
Adverse event	FRACTURED LEFT HIP
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)	26 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	True
Hospital Admission Date (dd MMM yyyy)	25 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	31 AUG 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	

v6.020 DTW (1102)

344 of 2309

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:16

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☒ Investigational Product ☐ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:16

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.

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

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:16

AEID	
Adverse event	FALL
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)	25 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 ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	347 of 2309

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:16

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☐ Related ☒ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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)

Generated On: 26 Nov 2020 11:01:16

AEID	
Adverse event	CONSTIPATION
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)	28 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)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:16

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field 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)

Generated On: 26 Nov 2020 11:01:16

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 ☐
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:16

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

Generated On: 26 Nov 2020 11:01:16

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)

Generated On: 26 Nov 2020 11:01:16

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 ☐ Intramuscular ☐

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:16

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1990
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:16

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 ☐ Intramuscular ☐

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:16

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1990
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:16

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 ☐ Intramuscular ☐

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:16

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1990
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:16

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 ☐ Intramuscular ☐

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:16

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:16

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 ☐ Intramuscular ☐

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:16

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1990
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:16

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 ☐ Intramuscular ☐

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:16

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1990
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:01:16

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 ☐ Intramuscular ☐

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:01:16

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1990
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:01:16

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 ☐ Intramuscular ☐

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:01:16

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1990
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:16

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 ☐
	Intramuscular ☐

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:16

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:16

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 ☐ Intramuscular ☐

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:16

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1990
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:01:16

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 ☐ Intramuscular ☐

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:01:16

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1990
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:01:16

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 ☐ Intramuscular ☐

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:01:16

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1990
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:01:16

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 ☐ Intraocular ☐

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:01:16

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1990
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:01:16

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 ☐
	Intramuscular ☐

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:01:16

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1990
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:01:16

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 ☐ Intramuscular ☐

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:01:16

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1990
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:01:16

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 ☐ Intramuscular ☐

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:01:16

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1990
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:01:16

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 ☐ Intraocular ☐

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:01:16

	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN NOV 2019	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		UN NOV 2019
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:01:16

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 ☐ Intraocular ☐

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:01:16

	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN NOV 2019	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	UN NOV 2019	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:01:16

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 ☐ Intraocular ☐

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:01:16

	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN NOV 2019	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	UN NOV 2019	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:01:16

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 ☐ Intramuscular ☐

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:01:16

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		28 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:01:16

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 ☐ Intramuscular ☐

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:01:16

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☒	No ☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:01:16

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 ☐
Intraocular ☐

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:01:16

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:01:16

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 ☐ Intraocular ☐

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:01:16

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy) 31 AUG 2020		
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 11:01:16

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 ☐ Intramuscular ☐

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 11:01:16

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		28 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		08 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 11:01:16

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 ☐ Intramuscular ☐

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 11:01:16

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		17 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:01:16

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3372005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 11:01:16

Procedure/Surgery date (<i>dd MMM yyyy</i>)	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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

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

Generated On: 26 Nov 2020 11:01:16

SAEID	USA-US056-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3372005

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

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:01:16

SAEID	USA-US056-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	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)

Generated On: 26 Nov 2020 11:01:16

SAEID	USA-US056-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	20/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)

Generated On: 26 Nov 2020 11:01:16

SAEID	USA-US056-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	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)

Generated On: 26 Nov 2020 11:01:16

SAEID	USA-US056-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	19/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)

Generated On: 26 Nov 2020 11:01:16

SAEID	USA-US056-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	20/OCT/2020 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)

Generated On: 26 Nov 2020 11:01:16

SAEID	USA-US056-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	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)

Generated On: 26 Nov 2020 11:01:16

SAEID	USA-US056-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	19/NOV/2020 17:03
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

Audit

US3372005 (Prod: Palm Beach Research Center)

US3372005

Form: Participant Creation

Generated On: 26 Nov 2020 11:01:16

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3372005'	RWS_ENDPOINT ENDPOINT (b) (4) 	31 Jul 2020 18:34:17

US3372005

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:28:36

US3372005

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
User entered '31 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	31 Jul 2020 18:34:18

US3372005

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:28:36

US3372005

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:16

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	31 Jul 2020 22:28:36

US3372005

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:16

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered (b) (6) 1925'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	31 Jul 2020 18:34:18

US3372005

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:16

[Age](#)

Audit	User	Time (GMT)
User entered '94'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:09

US3372005

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:16

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	31 Jul 2020 22:29:09

US3372005

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:16

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '94'	System	31 Jul 2020 22:29:21

US3372005

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:16

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:09

US3372005

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:16

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:09

US3372005

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:16

White

Audit	User	Time (GMT)
User entered '1'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:09

US3372005

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:16

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:09

US3372005

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:16

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:09

US3372005

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:16

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:09

US3372005

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:16

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:09

US3372005

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:16

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:09

US3372005

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:16

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:09

US3372005

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:16

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:09

US3372005

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:16

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:09

US3372005

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:16

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:21

US3372005

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
User entered 'Jul 2020'	System	31 Jul 2020 22:29:21

US3372005

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
User entered '2020'	System	31 Jul 2020 22:29:21

US3372005

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:16

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:21

US3372005

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:21

US3372005

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:16

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:21

US3372005

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:16

[If reason for screen fail is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:21

US3372005

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:16

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:21

US3372005

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:16

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	31 Jul 2020 18:34:18

US3372005

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:16

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 22:29:33

US3372005

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:01:16

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:33

US3372005

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:01:16

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:29:54

US3372005

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:16

Condition

Audit	User	Time (GMT)
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	Peter Jacob (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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
User entered 'un UNK 1995'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:30:21

US3372005

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:30:21

US3372005

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:30:21

US3372005

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
User entered 'un UNK 1995'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:30:21

US3372005

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:30:21

US3372005

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:16

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	31 Jul 2020 22:30:21

US3372005

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:16

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1995'	System	31 Jul 2020 22:30:21

US3372005

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:16

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	31 Jul 2020 22:30:21

US3372005

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:16

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1995'	System	31 Jul 2020 22:30:21

US3372005

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:16

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3372005

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
User entered 'un UNK 2009'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:30:44

US3372005

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:30:44

US3372005

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:30:44

US3372005

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
User entered 'un UNK 2009'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:30:44

US3372005

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:30:44

US3372005

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:16

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	31 Jul 2020 22:30:44

US3372005

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:16

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2009'	System	31 Jul 2020 22:30:44

US3372005

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:16

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	31 Jul 2020 22:30:44

US3372005

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:16

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2009'	System	31 Jul 2020 22:30:44

US3372005

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:16

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3372005

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
User entered 'un UNK 2009'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:31:00

US3372005

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:31:00

US3372005

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:31:00

US3372005

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:16

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2009'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:31:00

US3372005

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:31:00

US3372005

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:16

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	31 Jul 2020 22:31:00

US3372005

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:16

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2009'	System	31 Jul 2020 22:31:00

US3372005

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:16

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	31 Jul 2020 22:31:00

US3372005

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:16

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2009'	System	31 Jul 2020 22:31:00

US3372005

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:16

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3372005

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:31:16

US3372005

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:31:16

US3372005

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:31:16

US3372005

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:16

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:31:16

US3372005

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:31:16

US3372005

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:16

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	31 Jul 2020 22:31:16

US3372005

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:16

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2018'	System	31 Jul 2020 22:31:16

US3372005

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:16

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	31 Jul 2020 22:31:16

US3372005

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:16

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2018'	System	31 Jul 2020 22:31:16

US3372005

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:16

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	31 Jul 2020 22:31:35

US3372005

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:31:35

US3372005

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:31:35

US3372005

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:31:35

US3372005

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:16

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:31:35

US3372005

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:31:35

US3372005

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:16

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	31 Jul 2020 22:31:35

US3372005

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:16

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2018'	System	31 Jul 2020 22:31:35

US3372005

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:16

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	31 Jul 2020 22:31:35

US3372005

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:16

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2018'	System	31 Jul 2020 22:31:35

US3372005

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:16

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3372005

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
User entered 'un UNK 1995'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:49:36

US3372005

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:49:36

US3372005

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:49:36

US3372005

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:16

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 1995'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:49:36

US3372005

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:49:36

US3372005

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:16

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	04 Aug 2020 20:49:36

US3372005

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:16

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1995'	System	04 Aug 2020 20:49:36

US3372005

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:16

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	04 Aug 2020 20:49:36

US3372005

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:16

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1995'	System	04 Aug 2020 20:49:36

US3372005

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:16

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3372005

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
User entered 'un UNK 1995'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:50:05

US3372005

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:50:05

US3372005

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:50:05

US3372005

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:16

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 1995'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:50:05

US3372005

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:50:05

US3372005

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:16

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	04 Aug 2020 20:50:05

US3372005

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:16

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1995'	System	04 Aug 2020 20:50:05

US3372005

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:16

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	04 Aug 2020 20:50:05

US3372005

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:16

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1995'	System	04 Aug 2020 20:50:05

US3372005

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:01:16

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: 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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
User entered 'un UNK 1995'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:50:20

US3372005

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:50:20

US3372005

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:01:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:50:20

US3372005

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:01:16

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 1995'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:50:20

US3372005

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:01:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:50:20

US3372005

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:01:16

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	04 Aug 2020 20:50:20

US3372005

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:01:16

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1995'	System	04 Aug 2020 20:50:20

US3372005

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:01:16

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	04 Aug 2020 20:50:20

US3372005

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:01:16

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1995'	System	04 Aug 2020 20:50:20

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:52'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 14:52'	System	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '162.6' cm	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: 26 Nov 2020 11:01:16

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '133.2' kg	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: 26 Nov 2020 11:01:16

BMI (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[BMI units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.1' C	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '58'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '14'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '126'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '67'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Jul 2020 22:32:30

US3372005

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:32:36

US3372005

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	30 Sep 2020 21:09:13
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	15 Sep 2020 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 is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	04 Aug 2020 16:50:54
User entered '31 Jul 2020'	Peter Jacob (b) (4)	31 Jul 2020 22:32:36

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:16

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:16

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:16

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:16

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:16

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:16

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:16

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:16

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:16

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:16

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:16

[Specify](#)

Audit	User	Time (GMT)
User entered '94 years old'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:16

No Risk Identified

Audit	User	Time (GMT)
User entered '1'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:16

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:16

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:16

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:16

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:16

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:16

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:16

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	31 Jul 2020 22:33:15

US3372005

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:01:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kimarie Lee-Russell (b) (4)	04 Aug 2020 16:50:54

US3372005

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
User entered '04 Aug 2020' reason for change: Data Entry Error	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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Kimarie Lee-Russell (b) (4)	04 Aug 2020 16:50:54

US3372005

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:01:16

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	04 Aug 2020 16:50:54

US3372005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
User entered '04 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	04 Aug 2020 16:49:39

US3372005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:16

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	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) [REDACTED]	04 Aug 2020 16:49:39

US3372005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:16

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	04 Aug 2020 16:49:39

US3372005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:16

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
User opened query 'Per CDM: per sponsor review, BMI $\geq$ 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: 26 Nov 2020 11:01:16

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	04 Aug 2020 16:51:23

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:16

Height

Audit	User	Time (GMT)
User entered '162.6' cm	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:16

Weight

Audit	User	Time (GMT)
User entered '61.2' kg	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:16

Height

Audit	User	Time (GMT)
User entered '162.6' cm	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:16

Weight

Audit	User	Time (GMT)
User entered '61.2' kg	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: 26 Nov 2020 11:01:16

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:16

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020'	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: 26 Nov 2020 11:01:16

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:25'	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: 26 Nov 2020 11:01:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C	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: 26 Nov 2020 11:01:16

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 11:01:16

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '66'	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: 26 Nov 2020 11:01:16

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '18'	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: 26 Nov 2020 11:01:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '126'	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: 26 Nov 2020 11:01:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:16

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '74'	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: 26 Nov 2020 11:01:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:16

Height

Audit	User	Time (GMT)
User entered '162.6' cm	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:16

Weight

Audit	User	Time (GMT)
User entered '61.2' kg	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:52:27

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:16

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:16

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020'	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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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) (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)	04 Aug 2020 20:53:38
User opened 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)	04 Aug 2020 20:53:12
User entered '13:50'	Peter Jacob (b) (4)	04 Aug 2020 20:53:12
	(b) (4)	

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.1' C	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: 26 Nov 2020 11:01:16

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 11:01:16

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '56'	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: 26 Nov 2020 11:01:16

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	04 Aug 2020 20:53:12

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '18'	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: 26 Nov 2020 11:01:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	04 Aug 2020 20:53:12

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:16

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '122'	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: 26 Nov 2020 11:01:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Aug 2020 20:53:12

US3372005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '70'	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: 26 Nov 2020 11:01:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Aug 2020 20:53:12

US3372005

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:53:48

US3372005

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '04 Aug 2020'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:53:48

US3372005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kimarie Lee-Russell (b) (4)	04 Aug 2020 17:35:41

US3372005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:16

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Kimarie Lee-Russell (b) (4)	04 Aug 2020 17:35:41

US3372005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
User entered empty.	Kimarie Lee-Russell (b) (4)	04 Aug 2020 17:35:41

US3372005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	04 Aug 2020 17:35:41

US3372005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '4 Aug 2020'	Kimarie Lee-Russell (b) (4)	04 Aug 2020 17:35:41

US3372005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:16

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '13:20'	Kimarie Lee-Russell (b) (4)	04 Aug 2020 17:35:41

US3372005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:16

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '4 Aug 2020 13:20'	System	04 Aug 2020 17:35:41

US3372005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Right Arm (RIGHT ARM)'	Kimarie Lee-Russell (b) (4)	04 Aug 2020 17:35:41

US3372005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:16

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	04 Aug 2020 17:35:41

US3372005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:16

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	04 Aug 2020 17:35:41

US3372005

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kimarie Lee-Russell (b) (4)	04 Aug 2020 17:36:31

US3372005

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Aug 2020' reason for change: Data Entry Error	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: 26 Nov 2020 11:01:16

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:45'	Kimarie Lee-Russell (b) (4)	04 Aug 2020 17:36:31

US3372005

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
User entered '04 Aug 2020'	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: 26 Nov 2020 11:01:16

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:16

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '12:42'	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: 26 Nov 2020 11:01:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:01:16

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Aug 2020 20:54:18

US3372005

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:01:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:55:15

US3372005

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:01:16

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 20:55:15

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	04 Aug 2020 18:07:01
User entered 'Yes (Y)'	System	04 Aug 2020 18:07:01

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	04 Aug 2020 18:07:01
User entered '97.0'	System	04 Aug 2020 18:07:01

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	04 Aug 2020 18:07:01
User entered '04 Aug 2020 14:06'	System	04 Aug 2020 18:07:01

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	05 Aug 2020 12:43:54
User entered 'Yes (Y)'	System	05 Aug 2020 12:43:54

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	05 Aug 2020 12:43:54
User entered '97.8'	System	05 Aug 2020 12:43:54

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	05 Aug 2020 12:43:54
User entered '05 Aug 2020 08:43'	System	05 Aug 2020 12:43:54

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	06 Aug 2020 13:26:05
User entered 'Yes (Y)'	System	06 Aug 2020 13:26:05

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	06 Aug 2020 13:26:05
User entered '97.5'	System	06 Aug 2020 13:26:05

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	06 Aug 2020 13:26:05
User entered '06 Aug 2020 09:26'	System	06 Aug 2020 13:26:05

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	07 Aug 2020 12:28:53
User entered 'Yes (Y)'	System	07 Aug 2020 12:28:53

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	07 Aug 2020 12:28:53
User entered '97.5'	System	07 Aug 2020 12:28:53

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	08 Aug 2020 00:51:41
User entered 'Yes (Y)'	System	08 Aug 2020 00:51:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	08 Aug 2020 00:51:41
User entered '97.8'	System	08 Aug 2020 00:51:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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'	System	08 Aug 2020 00:51:41
User entered 'No (N)'	System	08 Aug 2020 00:51:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	08 Aug 2020 00:51:41
User entered '07 Aug 2020 20:51'	System	08 Aug 2020 00:51:41

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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-effe-4336-8c33-ea97455761a6'	System	08 Aug 2020 23:20:04
User entered 'Yes (Y)'	System	08 Aug 2020 23:20:04

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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-effe-4336-8c33-ea97455761a6'	System	08 Aug 2020 23:20:04
User entered '97.8'	System	08 Aug 2020 23:20:04

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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-effe-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: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	10 Aug 2020 00:51:53
User entered 'Yes (Y)'	System	10 Aug 2020 00:51:53

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	10 Aug 2020 00:51:53
User entered '97.8'	System	10 Aug 2020 00:51:53

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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'	System	10 Aug 2020 00:51:53
User entered 'No (N)'	System	10 Aug 2020 00:51:53

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	10 Aug 2020 00:51:53
User entered '09 Aug 2020 20:51'	System	10 Aug 2020 00:51:53

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	11 Aug 2020 00:18:28
User entered 'Yes (Y)'	System	11 Aug 2020 00:18:28

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	11 Aug 2020 00:18:28
User entered '98.0'	System	11 Aug 2020 00:18:28

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	11 Aug 2020 00:18:28
User entered '10 Aug 2020 20:18'	System	11 Aug 2020 00:18:28

US3372005

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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'	System	04 Aug 2020 18:07:37
User entered 'No (N)'	System	04 Aug 2020 18:07:37

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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'	System	04 Aug 2020 18:07:37
User entered 'No (N)'	System	04 Aug 2020 18:07:37

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	04 Aug 2020 18:07:37
User entered '04 Aug 2020 14:07'	System	04 Aug 2020 18:07:37

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	05 Aug 2020 12:44:36
User entered '05 Aug 2020 08:44'	System	05 Aug 2020 12:44:36

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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'	System	06 Aug 2020 13:26:38
User entered 'None (1)'	System	06 Aug 2020 13:26:38

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	06 Aug 2020 13:26:38
User entered 'No (N)'	System	06 Aug 2020 13:26:38

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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'	System	06 Aug 2020 13:26:38
User entered 'No (N)'	System	06 Aug 2020 13:26:38

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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'	System	06 Aug 2020 13:26:38
User entered 'None (1)'	System	06 Aug 2020 13:26:38

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	06 Aug 2020 13:26:38
User entered '06 Aug 2020 09:26'	System	06 Aug 2020 13:26:38

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	10 Aug 2020 00:52:26
User entered '09 Aug 2020 20:52'	System	10 Aug 2020 00:52:26

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	11 Aug 2020 00:18:57
User entered '10 Aug 2020 20:18'	System	11 Aug 2020 00:18:57

US3372005

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

FATIGUE

Audit	User	Time (GMT)
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-8805-83a56683aedd'	System	04 Aug 2020 18:08:24
User entered 'None (0)'	System	04 Aug 2020 18:08:24

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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-8805-83a56683aedd'	System	04 Aug 2020 18:08:24
User entered 'None (0)'	System	04 Aug 2020 18:08:24

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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-8805-83a56683aedd'	System	04 Aug 2020 18:08:24
User entered 'None (0)'	System	04 Aug 2020 18:08:24

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
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-8805-83a56683aedd'	System	04 Aug 2020 18:08:24
User entered 'None (0)'	System	04 Aug 2020 18:08:24

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

CHILLS

Audit	User	Time (GMT)
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-8805-83a56683aedd'	System	04 Aug 2020 18:08:24
User entered 'None (0)'	System	04 Aug 2020 18:08:24

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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'	System	04 Aug 2020 18:08:24
User entered 'No (N)'	System	04 Aug 2020 18:08:24

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

[PC Time stamp](#)

Audit	User	Time (GMT)
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-8805-83a56683aedd'	System	04 Aug 2020 18:08:24
User entered '04 Aug 2020 14:08'	System	04 Aug 2020 18:08:24

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

HEADACHE

Audit	User	Time (GMT)
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'	System	05 Aug 2020 12:45:16
User entered 'None (0)'	System	05 Aug 2020 12:45:16

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:16

FATIGUE

Audit	User	Time (GMT)
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'	System	05 Aug 2020 12:45:16
User entered 'None (0)'	System	05 Aug 2020 12:45:16

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	05 Aug 2020 12:45:16
User entered 'None (0)'	System	05 Aug 2020 12:45:16

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	05 Aug 2020 12:45:16
User entered 'None (0)'	System	05 Aug 2020 12:45:16

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	05 Aug 2020 12:45:16
User entered 'None (0)'	System	05 Aug 2020 12:45:16

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:16

CHILLS

Audit	User	Time (GMT)
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'	System	05 Aug 2020 12:45:16
User entered 'None (0)'	System	05 Aug 2020 12:45:16

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	05 Aug 2020 12:45:16
User entered '05 Aug 2020 08:45'	System	05 Aug 2020 12:45:16

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:01:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:01:16

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	06 Aug 2020 13:27:23
User entered '06 Aug 2020 09:27'	System	06 Aug 2020 13:27:23

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

HEADACHE

Audit	User	Time (GMT)
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'	System	07 Aug 2020 12:30:30
User entered 'None (0)'	System	07 Aug 2020 12:30:30

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:16

FATIGUE

Audit	User	Time (GMT)
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'	System	07 Aug 2020 12:30:30
User entered 'None (0)'	System	07 Aug 2020 12:30:30

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	07 Aug 2020 12:30:30
User entered 'None (0)'	System	07 Aug 2020 12:30:30

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	07 Aug 2020 12:30:30
User entered 'None (0)'	System	07 Aug 2020 12:30:30

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	07 Aug 2020 12:30:30
User entered 'None (0)'	System	07 Aug 2020 12:30:30

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:16

CHILLS

Audit	User	Time (GMT)
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'	System	07 Aug 2020 12:30:30
User entered 'None (0)'	System	07 Aug 2020 12:30:30

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

HEADACHE

Audit	User	Time (GMT)
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'	System	08 Aug 2020 00:53:06
User entered 'None (0)'	System	08 Aug 2020 00:53:06

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:16

FATIGUE

Audit	User	Time (GMT)
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'	System	08 Aug 2020 00:53:06
User entered 'None (0)'	System	08 Aug 2020 00:53:06

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	08 Aug 2020 00:53:06
User entered 'None (0)'	System	08 Aug 2020 00:53:06

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	08 Aug 2020 00:53:06
User entered 'None (0)'	System	08 Aug 2020 00:53:06

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:16

CHILLS

Audit	User	Time (GMT)
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'	System	08 Aug 2020 00:53:06
User entered 'None (0)'	System	08 Aug 2020 00:53:06

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	08 Aug 2020 00:53:06
User entered '07 Aug 2020 20:53'	System	08 Aug 2020 00:53:06

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

HEADACHE

Audit	User	Time (GMT)
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'	System	10 Aug 2020 00:53:23
User entered 'None (0)'	System	10 Aug 2020 00:53:23

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:16

FATIGUE

Audit	User	Time (GMT)
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'	System	10 Aug 2020 00:53:23
User entered 'None (0)'	System	10 Aug 2020 00:53:23

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	10 Aug 2020 00:53:23
User entered 'None (0)'	System	10 Aug 2020 00:53:23

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	10 Aug 2020 00:53:23
User entered 'None (0)'	System	10 Aug 2020 00:53:23

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:16

CHILLS

Audit	User	Time (GMT)
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'	System	10 Aug 2020 00:53:23
User entered 'None (0)'	System	10 Aug 2020 00:53:23

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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'	System	10 Aug 2020 00:53:23
User entered 'No (N)'	System	10 Aug 2020 00:53:23

US3372005

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:16

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:01:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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'	System	12 Aug 2020 00:34:46
User entered 'None (0)'	System	12 Aug 2020 00:34:46

US3372005

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 11:01:16

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	12 Aug 2020 00:34:46
User entered '11 Aug 2020 20:34'	System	12 Aug 2020 00:34:46

US3372005

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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'	System	12 Aug 2020 00:34:59
User entered 'No (N)'	System	12 Aug 2020 00:34:59

US3372005

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:01:16

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	12 Aug 2020 00:34:59
User entered '11 Aug 2020 20:34'	System	12 Aug 2020 00:34:59

US3372005

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	20 Aug 2020 02:11:50

US3372005

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Alexandra Arango (b) (4) (b) (4)	20 Aug 2020 02:11:50

US3372005

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Alexandra Arango (b) (4) (b) (4)	20 Aug 2020 02:11:50

US3372005

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Alexandra Arango (b) (4) (b) (4)	20 Aug 2020 02:11:50

US3372005

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	20 Aug 2020 23:15:15

US3372005

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:16

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 23:15:15

US3372005

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	21 Aug 2020 12:56:45

US3372005

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020'	Alexandra Arango (b) (4) (b) (4)	21 Aug 2020 12:56:45

US3372005

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Alexandra Arango (b) (4) (b) (4)	21 Aug 2020 12:56:45

US3372005

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Alexandra Arango (b) (4) (b) (4)	21 Aug 2020 12:56:45

US3372005

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	21 Aug 2020 12:56:52

US3372005

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:16

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 12:56:52

US3372005

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	26 Aug 2020 13:15:37

US3372005

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Aug 2020'	Alexandra Arango (b) (4) (b) (4)	26 Aug 2020 13:15:37

US3372005

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Alexandra Arango (b) (4) (b) (4)	26 Aug 2020 13:15:37

US3372005

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Alexandra Arango (b) (4) (b) (4)	26 Aug 2020 13:15:37

US3372005

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	26 Aug 2020 13:15:41

US3372005

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:16

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 13:15:41

US3372005

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elena Acosta (b) (4) (b) (4)	15 Sep 2020 19:09:39

US3372005

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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), (b) (6)	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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Elena Acosta (b) (4) (b) (4)	15 Sep 2020 19:09:39

US3372005

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:16

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	15 Sep 2020 19:09:39

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:16

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:16

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	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: 26 Nov 2020 11:01:16

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '13:40'	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: 26 Nov 2020 11:01:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.4' C	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: 26 Nov 2020 11:01:16

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 11:01:16

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '64'	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: 26 Nov 2020 11:01:16

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	25 Sep 2020 18:18:43

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '17'	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: 26 Nov 2020 11:01:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '118'	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: 26 Nov 2020 11:01:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Sep 2020 18:18:43

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:16

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '67'	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: 26 Nov 2020 11:01:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Sep 2020 18:18:43

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:16

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	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: 26 Nov 2020 11:01:16

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '16:05'	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: 26 Nov 2020 11:01:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Temperature (xxx.x)

Audit	User	Time (GMT)
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) (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.'	Peter Jacob (b) (4)	25 Sep 2020 18:19:07
answered with 'ncs' (Site from System).	(b) (4)	
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)	25 Sep 2020 18:19:03
	(b) (4)	

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:16

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 11:01:16

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '65'	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: 26 Nov 2020 11:01:16

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	25 Sep 2020 18:19:03

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '17'	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: 26 Nov 2020 11:01:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '119'	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: 26 Nov 2020 11:01:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Sep 2020 18:19:03

US3372005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:16

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '77'	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: 26 Nov 2020 11:01:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Sep 2020 18:19:03

US3372005

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:19:15

US3372005

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:16

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:19:15

US3372005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elena Acosta (b) (4) (b) (4)	15 Sep 2020 19:32:15

US3372005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:16

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Elena Acosta (b) (4) (b) (4)	15 Sep 2020 19:32:15

US3372005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
User entered empty.	Elena Acosta (b) (4) (b) (4)	15 Sep 2020 19:32:15

US3372005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	15 Sep 2020 19:32:15

US3372005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:16

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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) (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)	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)	15 Sep 2020 19:32:15

US3372005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:16

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '15:28'	Elena Acosta (b) (4) (b) (4)	15 Sep 2020 19:32:15

US3372005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:16

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
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).	System	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).	System	15 Sep 2020 19:32:15
User entered 'Left Arm (LEFT ARM)'	Elena Acosta (b) (4)	15 Sep 2020 19:32:15

US3372005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:16

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	15 Sep 2020 19:32:15

US3372005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:16

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	15 Sep 2020 19:32:15

US3372005

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:19:25

US3372005

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:19:25

US3372005

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:16

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:31'	Peter Jacob (b) (4) (b) (4)	25 Sep 2020 18:19:25

US3372005

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	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: 26 Nov 2020 11:01:16

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:16

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '14:27'	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: 26 Nov 2020 11:01:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:01:16

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 18:19:35

US3372005

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	18 Sep 2020 17:12:28

US3372005

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:16

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 17:12:28

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	15 Sep 2020 20:06:24
User entered 'Yes (Y)'	System	15 Sep 2020 20:06:24

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	15 Sep 2020 20:06:24
User entered '96.6'	System	15 Sep 2020 20:06:24

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	15 Sep 2020 20:06:24
User entered '15 Sep 2020 16:06'	System	15 Sep 2020 20:06:24

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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'	System	15 Sep 2020 23:16:57
User entered 'No (N)'	System	15 Sep 2020 23:16:57

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	17 Sep 2020 04:44:07
User entered 'Yes (Y)'	System	17 Sep 2020 04:44:07

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	17 Sep 2020 04:44:07
User entered '97.8'	System	17 Sep 2020 04:44:07

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	17 Sep 2020 04:44:07
User entered '17 Sep 2020 00:44'	System	17 Sep 2020 04:44:07

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	17 Sep 2020 16:30:11
User entered 'Yes (Y)'	System	17 Sep 2020 16:30:11

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	17 Sep 2020 16:30:11
User entered '97.8'	System	17 Sep 2020 16:30:11

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	18 Sep 2020 20:26:39
User entered 'Yes (Y)'	System	18 Sep 2020 20:26:39

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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'	System	18 Sep 2020 20:26:39
User entered 'No (N)'	System	18 Sep 2020 20:26:39

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	18 Sep 2020 20:26:39
User entered '18 Sep 2020 16:26'	System	18 Sep 2020 20:26:39

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	20 Sep 2020 01:02:41
User entered 'Yes (Y)'	System	20 Sep 2020 01:02:41

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	20 Sep 2020 01:02:41
User entered '97.8'	System	20 Sep 2020 01:02:41

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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'	System	20 Sep 2020 01:02:41
User entered 'No (N)'	System	20 Sep 2020 01:02:41

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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-aaa46b14016d'	System	20 Sep 2020 01:02:41
User entered '19 Sep 2020 21:02'	System	20 Sep 2020 01:02:41

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	20 Sep 2020 17:33:23
User entered 'Yes (Y)'	System	20 Sep 2020 17:33:23

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	20 Sep 2020 17:33:23
User entered '98.0'	System	20 Sep 2020 17:33:23

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	20 Sep 2020 17:33:23
User entered '20 Sep 2020 13:33'	System	20 Sep 2020 17:33:23

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	21 Sep 2020 20:29:24
User entered '98.0'	System	21 Sep 2020 20:29:24

US3372005

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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'	System	15 Sep 2020 20:13:29
User entered 'None (1)'	System	15 Sep 2020 20:13:29

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	15 Sep 2020 20:13:29
User entered 'No (N)'	System	15 Sep 2020 20:13:29

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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'	System	15 Sep 2020 20:13:29
User entered 'No (N)'	System	15 Sep 2020 20:13:29

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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'	System	15 Sep 2020 20:13:29
User entered 'None (1)'	System	15 Sep 2020 20:13:29

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	15 Sep 2020 20:13:29
User entered '15 Sep 2020 16:13'	System	15 Sep 2020 20:13:29

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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'	System	15 Sep 2020 23:18:01
User entered 'None (1)'	System	15 Sep 2020 23:18:01

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	15 Sep 2020 23:18:01
User entered 'No (N)'	System	15 Sep 2020 23:18:01

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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'	System	15 Sep 2020 23:18:01
User entered 'No (N)'	System	15 Sep 2020 23:18:01

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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'	System	15 Sep 2020 23:18:01
User entered 'None (1)'	System	15 Sep 2020 23:18:01

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	15 Sep 2020 23:18:01
User entered '15 Sep 2020 19:17'	System	15 Sep 2020 23:18:01

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	17 Sep 2020 04:45:14
User entered 'No (N)'	System	17 Sep 2020 04:45:14

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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'	System	17 Sep 2020 04:45:14
User entered 'No (N)'	System	17 Sep 2020 04:45:14

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	18 Sep 2020 20:27:08
User entered '18 Sep 2020 16:27'	System	18 Sep 2020 20:27:08

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	20 Sep 2020 01:02:12
User entered '19 Sep 2020 21:02'	System	20 Sep 2020 01:02:12

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	20 Sep 2020 17:33:49
User entered 'No (N)'	System	20 Sep 2020 17:33:49

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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'	System	20 Sep 2020 17:33:49
User entered 'No (N)'	System	20 Sep 2020 17:33:49

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	20 Sep 2020 17:33:49
User entered '20 Sep 2020 13:33'	System	20 Sep 2020 17:33:49

US3372005

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

HEADACHE

Audit	User	Time (GMT)
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'	System	15 Sep 2020 20:07:28
User entered 'None (0)'	System	15 Sep 2020 20:07:28

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

FATIGUE

Audit	User	Time (GMT)
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'	System	15 Sep 2020 20:07:28
User entered 'None (0)'	System	15 Sep 2020 20:07:28

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	15 Sep 2020 20:07:28
User entered 'None (0)'	System	15 Sep 2020 20:07:28

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	15 Sep 2020 20:07:28
User entered 'None (0)'	System	15 Sep 2020 20:07:28

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	15 Sep 2020 20:07:28
User entered 'None (0)'	System	15 Sep 2020 20:07:28

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

CHILLS

Audit	User	Time (GMT)
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'	System	15 Sep 2020 20:07:28
User entered 'None (0)'	System	15 Sep 2020 20:07:28

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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'	System	15 Sep 2020 20:07:28
User entered 'No (N)'	System	15 Sep 2020 20:07:28

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	15 Sep 2020 20:07:28
User entered '15 Sep 2020 16:07'	System	15 Sep 2020 20:07:28

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

HEADACHE

Audit	User	Time (GMT)
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'	System	15 Sep 2020 23:18:56
User entered 'None (0)'	System	15 Sep 2020 23:18:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:16

FATIGUE

Audit	User	Time (GMT)
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'	System	15 Sep 2020 23:18:56
User entered 'None (0)'	System	15 Sep 2020 23:18:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	15 Sep 2020 23:18:56
User entered 'None (0)'	System	15 Sep 2020 23:18:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	15 Sep 2020 23:18:56
User entered 'None (0)'	System	15 Sep 2020 23:18:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	15 Sep 2020 23:18:56
User entered 'None (0)'	System	15 Sep 2020 23:18:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:16

CHILLS

Audit	User	Time (GMT)
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'	System	15 Sep 2020 23:18:56
User entered 'None (0)'	System	15 Sep 2020 23:18:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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'	System	15 Sep 2020 23:18:56
User entered 'No (N)'	System	15 Sep 2020 23:18:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:16

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	15 Sep 2020 23:18:56
User entered '15 Sep 2020 19:18'	System	15 Sep 2020 23:18:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

HEADACHE

Audit	User	Time (GMT)
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'	System	17 Sep 2020 04:46:17
User entered 'None (0)'	System	17 Sep 2020 04:46:17

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:16

FATIGUE

Audit	User	Time (GMT)
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'	System	17 Sep 2020 04:46:17
User entered 'None (0)'	System	17 Sep 2020 04:46:17

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	17 Sep 2020 04:46:17
User entered 'None (0)'	System	17 Sep 2020 04:46:17

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	17 Sep 2020 04:46:17
User entered 'None (0)'	System	17 Sep 2020 04:46:17

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	17 Sep 2020 04:46:17
User entered 'None (0)'	System	17 Sep 2020 04:46:17

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:16

CHILLS

Audit	User	Time (GMT)
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'	System	17 Sep 2020 04:46:17
User entered 'None (0)'	System	17 Sep 2020 04:46:17

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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'	System	17 Sep 2020 04:46:17
User entered 'No (N)'	System	17 Sep 2020 04:46:17

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:16

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	17 Sep 2020 04:46:17
User entered '17 Sep 2020 00:46'	System	17 Sep 2020 04:46:17

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

HEADACHE

Audit	User	Time (GMT)
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'	System	17 Sep 2020 16:31:42
User entered 'None (0)'	System	17 Sep 2020 16:31:42

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:16

FATIGUE

Audit	User	Time (GMT)
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'	System	17 Sep 2020 16:31:42
User entered 'None (0)'	System	17 Sep 2020 16:31:42

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	17 Sep 2020 16:31:42
User entered 'None (0)'	System	17 Sep 2020 16:31:42

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	17 Sep 2020 16:31:42
User entered 'None (0)'	System	17 Sep 2020 16:31:42

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	17 Sep 2020 16:31:42
User entered 'None (0)'	System	17 Sep 2020 16:31:42

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:16

CHILLS

Audit	User	Time (GMT)
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'	System	17 Sep 2020 16:31:42
User entered 'None (0)'	System	17 Sep 2020 16:31:42

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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'	System	17 Sep 2020 16:31:42
User entered 'No (N)'	System	17 Sep 2020 16:31:42

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:16

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	17 Sep 2020 16:31:42
User entered '17 Sep 2020 12:31'	System	17 Sep 2020 16:31:42

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

HEADACHE

Audit	User	Time (GMT)
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'	System	18 Sep 2020 20:27:56
User entered 'None (0)'	System	18 Sep 2020 20:27:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:16

FATIGUE

Audit	User	Time (GMT)
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'	System	18 Sep 2020 20:27:56
User entered 'None (0)'	System	18 Sep 2020 20:27:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	18 Sep 2020 20:27:56
User entered 'None (0)'	System	18 Sep 2020 20:27:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	18 Sep 2020 20:27:56
User entered 'None (0)'	System	18 Sep 2020 20:27:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	18 Sep 2020 20:27:56
User entered 'None (0)'	System	18 Sep 2020 20:27:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:16

CHILLS

Audit	User	Time (GMT)
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'	System	18 Sep 2020 20:27:56
User entered 'None (0)'	System	18 Sep 2020 20:27:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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'	System	18 Sep 2020 20:27:56
User entered 'No (N)'	System	18 Sep 2020 20:27:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:16

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	18 Sep 2020 20:27:56
User entered '18 Sep 2020 16:27'	System	18 Sep 2020 20:27:56

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

HEADACHE

Audit	User	Time (GMT)
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'	System	20 Sep 2020 01:03:24
User entered 'None (0)'	System	20 Sep 2020 01:03:24

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:16

FATIGUE

Audit	User	Time (GMT)
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'	System	20 Sep 2020 01:03:24
User entered 'None (0)'	System	20 Sep 2020 01:03:24

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	20 Sep 2020 01:03:24
User entered 'None (0)'	System	20 Sep 2020 01:03:24

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	20 Sep 2020 01:03:24
User entered 'None (0)'	System	20 Sep 2020 01:03:24

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	20 Sep 2020 01:03:24
User entered 'None (0)'	System	20 Sep 2020 01:03:24

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:16

CHILLS

Audit	User	Time (GMT)
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'	System	20 Sep 2020 01:03:24
User entered 'None (0)'	System	20 Sep 2020 01:03:24

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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'	System	20 Sep 2020 01:03:24
User entered 'No (N)'	System	20 Sep 2020 01:03:24

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:16

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	20 Sep 2020 01:03:24
User entered '19 Sep 2020 21:03'	System	20 Sep 2020 01:03:24

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

HEADACHE

Audit	User	Time (GMT)
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'	System	20 Sep 2020 17:34:37
User entered 'None (0)'	System	20 Sep 2020 17:34:37

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:16

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	20 Sep 2020 17:34:37
User entered 'None (0)'	System	20 Sep 2020 17:34:37

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	20 Sep 2020 17:34:37
User entered 'None (0)'	System	20 Sep 2020 17:34:37

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	20 Sep 2020 17:34:37
User entered 'None (0)'	System	20 Sep 2020 17:34:37

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:16

CHILLS

Audit	User	Time (GMT)
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'	System	20 Sep 2020 17:34:37
User entered 'None (0)'	System	20 Sep 2020 17:34:37

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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'	System	20 Sep 2020 17:34:37
User entered 'No (N)'	System	20 Sep 2020 17:34:37

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:16

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

FATIGUE

Audit	User	Time (GMT)
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

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	21 Sep 2020 20:30:30
User entered 'None (0)'	System	21 Sep 2020 20:30:30

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	21 Sep 2020 20:30:30
User entered 'None (0)'	System	21 Sep 2020 20:30:30

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:16

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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'	System	21 Sep 2020 20:30:30
User entered 'No (N)'	System	21 Sep 2020 20:30:30

US3372005

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:16

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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).	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) (b) (4)	04 Oct 2020 13:01:14
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	18 Sep 2020 17:12:59

US3372005

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	David Scott (b) (4)	04 Oct 2020 14:01:12
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	David Scott (b) (4)	04 Oct 2020 13:01:14
User entered 'Contact Made (CONTACT MADE)'	Alexandra Arango (b) (4)	18 Sep 2020 17:12:59

US3372005

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	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) (b) (4)	04 Oct 2020 13:02:07
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	04 Oct 2020 13:01:14
Please review and reconcile.' (Site from System). User entered empty.	Alexandra Arango (b) (4) (b) (4)	18 Sep 2020 17:12:59

US3372005

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	18 Sep 2020 17:13:40

US3372005

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:16

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 17:13:40

US3372005

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	David Scott (b) (4) (b) (4)	04 Oct 2020 13:00:39

US3372005

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
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) (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.'	Peter Jacob (b) (4)	09 Oct 2020 18:07:23
answered with 'per monitor we were told to stay on schedule and make the calls based on Visit 1 treatment date' (Site from System).	(b) (4)	
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)	04 Oct 2020 13:00:39
	(b) (4)	

US3372005

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	David Scott (b) (4) (b) (4)	04 Oct 2020 13:00:39

US3372005

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	David Scott (b) (4) (b) (4)	04 Oct 2020 13:00:39

US3372005

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	23 Sep 2020 22:47:20

US3372005

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:16

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 22:47:20

US3372005

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	23 Sep 2020 22:47:30

US3372005

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
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) (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.'	Alexandra Arango (b) (4)	23 Sep 2020 22:47:43
answered with 'Phone visit was completed within window per protocol.' (Site from System).	(b) (4)	
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)	23 Sep 2020 22:47:30
	(b) (4)	

US3372005

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Alexandra Arango (b) (4) (b) (4)	23 Sep 2020 22:47:30

US3372005

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Alexandra Arango (b) (4) (b) (4)	23 Sep 2020 22:47:30

US3372005

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	23 Sep 2020 22:47:54

US3372005

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:16

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 22:47:54

US3372005

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kimarie Lee-Russell (b) (4)	29 Sep 2020 15:26:34

US3372005

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:16

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 06:53:00
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.'	Kimarie Lee-Russell	29 Sep 2020 15:27:16
answered with 'Date is correct. ' (Site from System).	(b) (4)	
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	29 Sep 2020 15:26:34
User entered '29 Sep 2020'	Kimarie Lee-Russell	29 Sep 2020 15:26:34
	(b) (4)	

US3372005

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Kimarie Lee-Russell (b) (4)	29 Sep 2020 15:26:34

US3372005

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:16

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	29 Sep 2020 15:26:34

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 15:51:03

US3372005

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Peter Jacob (b) (4)	15 Oct 2020 16:27:37
User entered 'Yes (Y)'	Peter Jacob (b) (4)	09 Oct 2020 15:53:20

US3372005

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	15 Oct 2020 16:27:37
User entered '29 Sep 2020'	Peter Jacob (b) (4)	09 Oct 2020 15:53:20

US3372005

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:53:32

US3372005

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:53:32

US3372005

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:16

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:42'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:53:32

US3372005

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:53:37

US3372005

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:16

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 15:53:37

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[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: '2020-10-06T12:00:52', 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: 26 Nov 2020 11:01:16

Have you been exposed to someone with 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: '2020-10-06T12:00:57', 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: 26 Nov 2020 11:01:16

[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: '2020-10-06T12:01:07', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '158b4fd3-42a0-47b4-83d3-9f7a62752f50'	System	06 Oct 2020 16:02:30
User entered '06 Oct 2020 12:01:07'	System	06 Oct 2020 16:02:30

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[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: '2020-10-13T12:01:31', 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: 26 Nov 2020 11:01:16

Have you been exposed to someone with 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: '2020-10-13T12:01:36', 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: 26 Nov 2020 11:01:16

[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: '2020-10-13T12:01:46', 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: 26 Nov 2020 11:01:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[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: '2020-10-20T15:03:27', 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: 26 Nov 2020 11:01:16

Have you been exposed to someone with 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: '2020-10-20T15:03:42', 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: 26 Nov 2020 11:01:16

[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: '2020-10-20T15:03:49', 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: 26 Nov 2020 11:01:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[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: '2020-11-01T21:47:47', 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: 26 Nov 2020 11:01:16

Have you been exposed to someone with 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: '2020-11-01T21:47:53', 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: 26 Nov 2020 11:01:16

[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: '2020-11-01T21:48:10', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: '2444cfd6-15a6-4095-ad32-cefb00788a78'	System	02 Nov 2020 02:48:16
User entered '01 Nov 2020 21:48:10'	System	02 Nov 2020 02:48:16

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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: '2020-11-09T22:21:05', 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: 26 Nov 2020 11:01:16

Have you been exposed to someone with 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: '2020-11-09T22:21:15', 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: 26 Nov 2020 11:01:16

[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: '2020-11-09T22:21:24', User OID: 'PatientReportedOutcome (US3372005)', ODM File OID: 'f9486f71-80d4-4e54-acc5-820956520e22'	System	10 Nov 2020 03:21:28
User entered '09 Nov 2020 22:21:24'	System	10 Nov 2020 03:21:28

US3372005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

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: '2020-11-16T22:23:49', 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: 26 Nov 2020 11:01:16

Have you been exposed to someone with 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: '2020-11-16T22:23:53', 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: 26 Nov 2020 11:01:16

[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: '2020-11-16T22:24:02', 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: 26 Nov 2020 11:01:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

[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 Oct 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: 26 Nov 2020 11:01:16

[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 Oct 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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

[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 Oct 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: 26 Nov 2020 11:01:16

[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 Oct 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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

[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 Oct 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: 26 Nov 2020 11:01:16

[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 Oct 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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

[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 Oct 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: 26 Nov 2020 11:01:16

[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 Oct 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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

[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 Oct 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: 26 Nov 2020 11:01:16

[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 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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

[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 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: 26 Nov 2020 11:01:16

[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 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: 26 Nov 2020 11:01:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:03:41
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 11:03:41

US3372005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:16

[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 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: 26 Nov 2020 11:01:16

[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 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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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'	System	20 Nov 2020 04:34:45
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: 26 Nov 2020 11:01:16

Have you been exposed to someone with 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'	System	20 Nov 2020 04:34:45
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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danielle Theodore (b) (4)	27 Oct 2020 18:20:15
	(b) (4)	
	(b) (4)	

US3372005

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
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) (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)	27 Oct 2020 18:20:15
	(b) (4)	
	(b) (4)	

US3372005

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Danielle Theodore (b) (4)	27 Oct 2020 18:20:15
	(b) (4)	
	(b) (4)	

US3372005

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Danielle Theodore (b) (4)	27 Oct 2020 18:20:15
	(b) (4)	
	(b) (4)	

US3372005

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danielle Theodore (b) (4) (b) (4) (b) (4)	27 Oct 2020 18:20:45

US3372005

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:16

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 18:20:45

US3372005

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:01:16

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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 'USA-US056-2020-mRNA-1273-P301000001'	System	31 Aug 2020 20:12:45
User entered 'New'	(b) (4), (b) (6)	31 Aug 2020 20:12:45

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:16

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 16:22:27
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Hip fracture, LLT: Fractured hip - version MedDRA\23.0.	Coder Import (b) (4) (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) (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, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Hip fracture, LLT: Fractured hip - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:13:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (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: 26 Nov 2020 11:01:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Death](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Life threatening](#)

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	03 Nov 2020 14:40:01
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).	Mary Sergalis (b) (4)	02 Nov 2020 14:52:30
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).	(b) (4), (b) (6)	30 Oct 2020 04:21:38
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: 26 Nov 2020 11:01:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 13:05:57
User entered '1'	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:16

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Other medically important event](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
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 19:30:28
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)	18 Nov 2020 17:04:17
DataPoint Un-verified.	Jennifer Torres (b) (4)	18 Nov 2020 17:03:46
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jennifer Torres (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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:16

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(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). 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).	(b) (4), (b) (6)	20 Sep 2020 20:13:06
DataPoint Un-verified.	Mary Sergalis (b) (4)	18 Sep 2020 16:01:54
	(b) (4), (b) (6)	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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:16

[None](#)

Audit	User	Time (GMT)
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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:48:47
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: 26 Nov 2020 11:01:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
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) (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.'	Mary Sergalis (b) (4)	17 Oct 2020 18:24:05
answered with 'Procedure added' (Site from DM).		
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 '1'	Mary Sergalis (b) (4)	31 Aug 2020 19:12:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:16

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	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: Data Entry Error DataPoint Verified.	Mary Sergalis (b) (4)	18 Sep 2020 16:01:07
	(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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Folder: Adverse Events

Form: Adverse Events (1)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[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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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:16

[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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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:16

[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

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:16

[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)

Generated On: 26 Nov 2020 11:01:16

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:16

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	31 Aug 2020 19:12:26

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:16

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	19 Oct 2020 14:36:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(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)

Generated On: 26 Nov 2020 11:01:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)

Generated On: 26 Nov 2020 11:01:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)

Generated On: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(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)

Generated On: 26 Nov 2020 11:01:16

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:16

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)

Generated On: 26 Nov 2020 11:01:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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)

Generated On: 26 Nov 2020 11:01:16

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:16

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)

Generated On: 26 Nov 2020 11:01:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)

Generated On: 26 Nov 2020 11:01:16

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 11:01:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
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)	18 Nov 2020 17:04:35
DataPoint Un-verified.	Jennifer Torres (b) (4)	18 Nov 2020 17:04:28
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jennifer Torres (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: 26 Nov 2020 11:01:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 14:35:33

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:16

[Adverse event](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[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)

Generated On: 26 Nov 2020 11:01:16

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 19:31:20
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)	18 Nov 2020 17:04:50
DataPoint Un-verified.	Jennifer Torres (b) (4)	18 Nov 2020 17:04:44
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jennifer Torres (b) (4)	18 Nov 2020 17:04:44
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 08:10:18
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: 26 Nov 2020 11:01:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '1'	Mary Sergalis (b) (4)	28 Oct 2020 17:57:01

US3372005

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:01:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[Adverse event](#)

Audit	User	Time (GMT)
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: Gastrooesophageal reflux disease, LLT: Gastrooesophageal 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) (b) (4) (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:16

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

End time (00:00-23:59)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:16

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	18 Nov 2020 17:05:06
DataPoint Un-verified.	Jennifer Torres (b) (4)	18 Nov 2020 17:04:59
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jennifer Torres (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: 26 Nov 2020 11:01:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:53:23
User entered '1'	Mary Sergalis (b) (4)	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Narrative](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Oct 2020 18:02:57

US3372005

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:01:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Oct 2020 18:02:57

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:01:16

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[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)	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)	02 Oct 2020 18:58:48

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:16

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: 26 Nov 2020 11:01:16

[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
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:16

[Prophylaxis](#)

Audit	User	Time (GMT)
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) (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)	04 Aug 2020 20:57:31

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:16

[Indication](#)

Audit	User	Time (GMT)
User entered 'dietary supplement'	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: 26 Nov 2020 11:01:16

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	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: 26 Nov 2020 11:01:16

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	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: 26 Nov 2020 11:01:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 11:01:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:01:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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) (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)	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)	04 Aug 2020 20:57:31

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:01:16

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[Name of Medication](#)

Audit	User	Time (GMT)
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.	Coder Import (b) (4) (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: 26 Nov 2020 11:01:16

[Prophylaxis](#)

Audit	User	Time (GMT)
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) (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)	04 Aug 2020 20:58:12

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:16

[Indication](#)

Audit	User	Time (GMT)
User entered 'dietary supplement'	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: 26 Nov 2020 11:01:16

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1000'	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: 26 Nov 2020 11:01:16

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 11:01:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 11:01:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:01:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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) (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.'	Peter Jacob (b) (4)	04 Aug 2020 20:58:17
answered with 'medication is ongoing' (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 20:58:12
User entered 'un UNK 1990'	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: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:01:16

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[Name of Medication](#)

Audit	User	Time (GMT)
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.	Coder Import (b) (4) (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 User entered 'vitamin B complex'	System Peter Jacob (b) (4) (b) (4)	04 Aug 2020 20:59:11 04 Aug 2020 20:59:01

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:16

[Prophylaxis](#)

Audit	User	Time (GMT)
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) (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)	04 Aug 2020 20:59:01

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:16

[Indication](#)

Audit	User	Time (GMT)
User entered 'dietary supplement'	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: 26 Nov 2020 11:01:16

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	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: 26 Nov 2020 11:01:16

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	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: 26 Nov 2020 11:01:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 11:01:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:01:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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) (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.'	Peter Jacob (b) (4)	04 Aug 2020 20:59:05
answered with 'medication is ongoing' (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 20:59:01
User entered 'un UNK 1990'	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: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:01:16

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[Name of Medication](#)

Audit	User	Time (GMT)
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.	Coder Import (b) (4) (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: 26 Nov 2020 11:01:16

[Prophylaxis](#)

Audit	User	Time (GMT)
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) (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)	04 Aug 2020 20:59:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:16

[Indication](#)

Audit	User	Time (GMT)
User entered 'dietary supplement'	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: 26 Nov 2020 11:01:16

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '2000'	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: 26 Nov 2020 11:01:16

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'IU (IU)'	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: 26 Nov 2020 11:01:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 11:01:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:01:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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) (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.'	Peter Jacob (b) (4)	04 Aug 2020 20:59:52
answered with 'medication is ongoing' (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 20:59:37
User entered 'un UNK 1990'	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: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:01:16

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	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)	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)	04 Aug 2020 21:00:26
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:16

[Prophylaxis](#)

Audit	User	Time (GMT)
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) (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)	04 Aug 2020 21:00:26

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:16

[Indication](#)

Audit	User	Time (GMT)
User entered 'dietary supplement'	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: 26 Nov 2020 11:01:16

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	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: 26 Nov 2020 11:01:16

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 11:01:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 11:01:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:01:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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) (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.'	Peter Jacob (b) (4)	04 Aug 2020 21:00:30
answered with 'medication is ongoing' (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 21:00:26
User entered 'un UNK 1990'	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: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:01:16

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[Name of Medication](#)

Audit	User	Time (GMT)
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.	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)	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)	04 Aug 2020 21:01:10
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:16

[Prophylaxis](#)

Audit	User	Time (GMT)
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) (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)	04 Aug 2020 21:01:10

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:16

[Indication](#)

Audit	User	Time (GMT)
User entered 'dietary supplement'	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: 26 Nov 2020 11:01:16

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '420'	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: 26 Nov 2020 11:01:16

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 11:01:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 11:01:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:01:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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) (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.'	Peter Jacob (b) (4)	04 Aug 2020 21:01:14
answered with 'medication is ongoing' (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 21:01:10
User entered 'un UNK 1990'	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: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:01:16

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: XANTOFYL, PRODUCTSYNONYM: LUTEIN [XANTOFYL] - version WHODrug-Global-B3\\202003.	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: 26 Nov 2020 11:01:16

[Prophylaxis](#)

Audit	User	Time (GMT)
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) (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)	04 Aug 2020 21:01:56

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:01:16

[Indication](#)

Audit	User	Time (GMT)
User entered 'dietary supplement'	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: 26 Nov 2020 11:01:16

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	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: 26 Nov 2020 11:01:16

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 11:01:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 11:01:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:01:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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) (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.'	Peter Jacob (b) (4)	04 Aug 2020 21:02:00
answered with 'medication is ongoing' (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 21:01:56
User entered 'un UNK 1990'	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: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:01:16

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[Name of Medication](#)

Audit	User	Time (GMT)
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 'lycopenine'	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: 26 Nov 2020 11:01:16

[Prophylaxis](#)

Audit	User	Time (GMT)
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) (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)	04 Aug 2020 21:02:33

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:01:16

[Indication](#)

Audit	User	Time (GMT)
User entered 'dietary supplement'	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: 26 Nov 2020 11:01:16

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '30'	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: 26 Nov 2020 11:01:16

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 11:01:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 11:01:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:01:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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) (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.'	Peter Jacob (b) (4)	04 Aug 2020 21:02:37
answered with 'medication is ongoing' (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 21:02:33
User entered 'un UNK 1990'	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: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:01:16

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[Name of Medication](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	04 Aug 2020 21:03:06

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:16

[Prophylaxis](#)

Audit	User	Time (GMT)
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) (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)	04 Aug 2020 21:03:06

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:16

[Indication](#)

Audit	User	Time (GMT)
User entered 'dietary supplement'	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: 26 Nov 2020 11:01:16

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	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: 26 Nov 2020 11:01:16

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 11:01:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 11:01:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:01:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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) (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.'	Peter Jacob (b) (4)	04 Aug 2020 21:03:11
answered with 'medication is ongoing' (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 21:03:06
User entered 'un UNK 1990'	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: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:01:16

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[Name of Medication](#)

Audit	User	Time (GMT)
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.	Coder Import (b) (4) (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: 26 Nov 2020 11:01:16

[Prophylaxis](#)

Audit	User	Time (GMT)
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) (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)	04 Aug 2020 21:03:44

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:16

[Indication](#)

Audit	User	Time (GMT)
User entered 'dietary supplement'	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: 26 Nov 2020 11:01:16

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '600'	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: 26 Nov 2020 11:01:16

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 11:01:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	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: 26 Nov 2020 11:01:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:01:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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) (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.'	Peter Jacob (b) (4)	04 Aug 2020 21:03:50
answered with 'medication is ongoing' (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 21:03:44
User entered 'un UNK 1990'	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: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:01:16

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[Name of Medication](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	04 Aug 2020 21:04:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:01:16

[Prophylaxis](#)

Audit	User	Time (GMT)
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) (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)	04 Aug 2020 21:04:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:01:16

[Indication](#)

Audit	User	Time (GMT)
User entered 'dietary supplement'	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: 26 Nov 2020 11:01:16

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '320'	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: 26 Nov 2020 11:01:16

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 11:01:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 11:01:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:01:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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) (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.'	Peter Jacob (b) (4)	04 Aug 2020 21:04:31
answered with 'medication is ongoing' (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 21:04:28
User entered 'un UNK 1990'	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: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:01:16

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: KRILL OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (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: 26 Nov 2020 11:01:16

[Prophylaxis](#)

Audit	User	Time (GMT)
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) (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)	04 Aug 2020 21:04:59

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:01:16

[Indication](#)

Audit	User	Time (GMT)
User entered 'dietary supplement'	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: 26 Nov 2020 11:01:16

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	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: 26 Nov 2020 11:01:16

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 11:01:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 11:01:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:01:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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) (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.'	Peter Jacob (b) (4)	04 Aug 2020 21:05:03
answered with 'medication is ongoing' (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 21:04:59
User entered 'un UNK 1990'	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: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:01:16

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

Name of Medication

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Prophylaxis](#)

Audit	User	Time (GMT)
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) (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)	04 Aug 2020 21:05:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:01:16

[Indication](#)

Audit	User	Time (GMT)
User entered 'dietary supplement'	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: 26 Nov 2020 11:01:16

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '260'	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: 26 Nov 2020 11:01:16

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)'	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: 26 Nov 2020 11:01:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 11:01:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:01:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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) (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.'	Peter Jacob (b) (4)	04 Aug 2020 21:05:41
answered with 'medication is ongoing' (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 21:05:37
User entered 'un UNK 1990'	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: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:01:16

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[Name of Medication](#)

Audit	User	Time (GMT)
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.	Coder Import (b) (4) (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: 26 Nov 2020 11:01:16

[Prophylaxis](#)

Audit	User	Time (GMT)
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) (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)	04 Aug 2020 21:06:08

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:01:16

[Indication](#)

Audit	User	Time (GMT)
User entered 'dietary supplement'	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: 26 Nov 2020 11:01:16

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '25'	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: 26 Nov 2020 11:01:16

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 11:01:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 11:01:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:01:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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) (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.'	Peter Jacob (b) (4)	04 Aug 2020 21:06:17
answered with 'medication is ongoing' (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 21:06:08
User entered 'un UNK 1990'	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: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:01:16

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[Name of Medication](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	04 Aug 2020 21:06:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:01:16

[Prophylaxis](#)

Audit	User	Time (GMT)
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) (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)	04 Aug 2020 21:06:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:01:16

[Indication](#)

Audit	User	Time (GMT)
User entered 'dietary supplement'	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: 26 Nov 2020 11:01:16

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1000'	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: 26 Nov 2020 11:01:16

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 11:01:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 11:01:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:01:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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) (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.'	Peter Jacob (b) (4)	04 Aug 2020 21:06:58
answered with 'medication is ongoing' (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 21:06:53
User entered 'un UNK 1990'	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: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:01:16

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[Name of Medication](#)

Audit	User	Time (GMT)
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.	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)	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)	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)	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)	04 Aug 2020 21:07:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:01:16

[Prophylaxis](#)

Audit	User	Time (GMT)
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) (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)	04 Aug 2020 21:07:37

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:01:16

[Indication](#)

Audit	User	Time (GMT)
User entered 'dietary supplement'	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: 26 Nov 2020 11:01:16

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1000'	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: 26 Nov 2020 11:01:16

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 11:01:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 11:01:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:01:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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) (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.'	Peter Jacob (b) (4)	04 Aug 2020 21:07:49
answered with 'medication is ongoing' (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 21:07:37
User entered 'un UNK 1990'	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: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:01:16

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	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) (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) (b) (4)	04 Aug 2020 21:08:53

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:01:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:16

[Indication](#)

Audit	User	Time (GMT)
User entered 'influenza prophylaxis/prevention'	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: 26 Nov 2020 11:01:16

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.25'	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: 26 Nov 2020 11:01:16

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	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: 26 Nov 2020 11:01:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	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: 26 Nov 2020 11:01:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	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: 26 Nov 2020 11:01:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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) (6)	16 Aug 2020 18:41:58
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: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:01:16

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:01:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un Nov 2019'	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: 26 Nov 2020 11:01:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:01:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Name of Medication](#)

Audit	User	Time (GMT)
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.	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: 26 Nov 2020 11:01:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:16

[Indication](#)

Audit	User	Time (GMT)
User entered 'pneumonia prophylaxis/prevention'	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: 26 Nov 2020 11:01:16

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.5' reason for change: Data Entry Error	Mary Sergalis (b) (4)	18 Sep 2020 16:14:27
User entered '1'	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: 26 Nov 2020 11:01:16

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	18 Sep 2020 16:14:27
User entered 'Other (OTHER)'	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: 26 Nov 2020 11:01:16

If dose unit is Other, specify

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 11:01:16

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	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: 26 Nov 2020 11:01:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	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: 26 Nov 2020 11:01:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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) (6)	16 Aug 2020 18:42:02
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 21:10:31
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 21:10:11
User entered 'un Nov 2019'	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: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:01:16

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:01:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un Nov 2019'	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: 26 Nov 2020 11:01:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:01:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Name of Medication](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	09 Oct 2020 15:57:29
Coding entries removed.	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:57:29
User entered 'herpes zoster VACCINE' reason for change: Data Entry Error	Peter Jacob (b) (4) (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) (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) (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) (b) (4)	04 Aug 2020 21:11:28

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:01:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:16

[Indication](#)

Audit	User	Time (GMT)
User entered 'herpes zoster PROPHYLAXIS/PREVENTION' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	09 Oct 2020 15:57:29
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: 26 Nov 2020 11:01:16

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.5' reason for change: Data Entry Error	Mary Sergalis (b) (4)	18 Sep 2020 16:15:35
User entered '1'	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: 26 Nov 2020 11:01:16

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	18 Sep 2020 16:15:35
User entered 'Other (OTHER)'	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: 26 Nov 2020 11:01:16

If dose unit is Other, specify

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 11:01:16

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	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: 26 Nov 2020 11:01:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	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: 26 Nov 2020 11:01:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
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) (6)	16 Aug 2020 18:42:05
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 21:11:32
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 21:11:28
User entered 'un Nov 2019'	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: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:01:16

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:01:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un Nov 2019'	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: 26 Nov 2020 11:01:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:01:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	18 Sep 2020 16:23:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder User entered 'Acetaminophen'	System	18 Sep 2020 16:22:53
	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: 26 Nov 2020 11:01:16

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (b) (4) (b) (4)	18 Sep 2020 16:27:00

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:01:16

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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: 26 Nov 2020 11:01:16

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (b) (4) (b) (4)	18 Sep 2020 16:30:18

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:01:16

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Name of Medication](#)

Audit	User	Time (GMT)
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.	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)	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)	09 Oct 2020 15:58:43
	(b) (4)	

US3372005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 11:01:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:01:16

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5'	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: 26 Nov 2020 11:01:16

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 11:01:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 11:01:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:01:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

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

Audit	User	Time (GMT)
User entered '17 Sep 2020'	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: 26 Nov 2020 11:01:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:01:16

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[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: 26 Nov 2020 11:01:16

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:53
User entered '1'	(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: 26 Nov 2020 11:01:16

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

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.

Audit	User	Time (GMT)
DataPoint Verified.	(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 '1'	(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: 26 Nov 2020 11:01:16

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

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.

Audit	User	Time (GMT)
DataPoint Verified.	(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 '1'	(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: 26 Nov 2020 11:01:16

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

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.

Audit	User	Time (GMT)
DataPoint Verified.	(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 '1'	(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: 26 Nov 2020 11:01:16

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

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.

Audit	User	Time (GMT)
DataPoint Verified.	(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 '1'	(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: 26 Nov 2020 11:01:16

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 17:03:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:06:39
User entered '1'	(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: 26 Nov 2020 11:01:16

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:16

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:38:17
User entered '1'	(b) (4), (b) (6)	19 Nov 2020 17:03:34