

US3402225 (Prod: Meridian Clinical Research, LLC)

Generated By: KC Joubran

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US3402225

Form: Participant Creation

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

[Participant ID](#)

US3402225

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

US3402225

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3402225

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Date of Birth (MMM yyyy)	(b) (6) 1972
Age	48
Age Units	YEARS
Age (Derived)	48
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 17:16:47

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Date of Informed Consent (*dd MMM yyyy*) 4 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 17:16:47

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Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 17:16:47

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Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 17:16:47

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Condition	MIGRAINES
Start date (dd MMM yyyy)	UN UNK 1983
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1983
Start Year (derived)	1983
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3402225

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Condition	LEFT SHOULDER PAIN
Start date (dd MMM yyyy)	UN MAR 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Condition	ENVIRONMENTAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	4 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:38 (24 HR)
Vital Signs Date and Time (derived)	4 AUG 2020 13:38
Height (<i>xxx.x</i>)	160.0 cm
Weight (<i>xxx.x</i>)	80.4 kg
BMI (<i>xxx.x</i>)	31.40625 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

4 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Date of assessment (*dd MMM yyyy*) 4 AUG 2020

Is the participant of childbearing potential? Yes
No

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Was the pregnancy test performed? Yes
No

Date of test (*dd MMM yyyy*) 4 AUG 2020

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

Collection date _____
Collection time _____
Collection date and time (derived) _____

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:16:47

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes No

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:16:47

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 4 AUG 2020

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

Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

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

What was the participant's randomization number? 100968

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk
 >=18 and <65 years and at risk
 >=65 years

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes No

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes No

Severe obesity (body mass index > or = 40kg/m2) Yes No

Diabetes (Type I, Type 2, or gestational) Yes No

Liver Disease Yes No

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	4 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:38 (24 HR)
Vital Signs Date and Time (derived)	4 AUG 2020 13:38
Temperature (<i>xxx.x</i>)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	82 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	4 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:30 (24 HR)
Vital Signs Date and Time (derived)	4 AUG 2020 15:30
Temperature (<i>xxx.x</i>)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	82 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

4 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: Pregnancy Test

Data signed: (b) (4) 26 Apr 2021 22:51:49

Generated On: 09 Jun 2021 17:23:40

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) _____

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3402225

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

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) 14:52 (24 HR)

Treatment Date and Time (derived) 4 AUG 2020 14:52

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	4 AUG 2020
Collection time (<i>00:00-23:59</i>)	14:26 (24 HR)
Collection date and time (derived)	4 AUG 2020 14:26

US3402225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Collection date (<i>dd MMM yyyy</i>)			4 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	14:23	4 AUG 2020 14:23
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 98.4 °F

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

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

PC Time Stamp 04 AUG 2020 15:36

PC Open Date & Time 04 AUG 2020 15:12

PC Close Date & Time 04 AUG 2020 17:42

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

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 98.0 °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 19:49
PC Open Date & Time 04 AUG 2020 18:37
PC Close Date & Time 05 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 2

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	05 AUG 2020 18:39
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	06 AUG 2020 19:20
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: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 4

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	07 AUG 2020 22:52
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 5

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	08 AUG 2020 22:59
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	09 AUG 2020 19:42
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	10 AUG 2020 21:31
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

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 15:39

PC Open Date & Time

04 AUG 2020 15:12

PC Close Date & Time

04 AUG 2020 17:42

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

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

04 AUG 2020 19:49

PC Open Date & Time

04 AUG 2020 18:37

PC Close Date & Time

05 AUG 2020 11:59

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 2

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	05 AUG 2020 18:39
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 3

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

06 AUG 2020 19:21

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

07 AUG 2020 22:53

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 5

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

08 AUG 2020 22:59

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

09 AUG 2020 19:42

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

10 AUG 2020 21:31

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

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

No

Yes

PC Time stamp	04 AUG 2020 15:40
PC Open Date & Time	04 AUG 2020 15:12
PC Close Date & Time	04 AUG 2020 17:42

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

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

No
Yes

PC Time stamp	04 AUG 2020 19:50
PC Open Date & Time	04 AUG 2020 18:37
PC Close Date & Time	05 AUG 2020 11:59

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:40

Yes

PC Time stamp	05 AUG 2020 18:39
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:40

	Yes <input type="checkbox"/>
PC Time stamp	06 AUG 2020 19:21
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:40

	Yes <input type="checkbox"/>
PC Time stamp	07 AUG 2020 22:53
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:40

	Yes <input type="checkbox"/>
PC Time stamp	08 AUG 2020 23:00
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:40

	Yes <input type="checkbox"/>
PC Time stamp	09 AUG 2020 19:43
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:40

	Yes <input type="checkbox"/>
PC Time stamp	10 AUG 2020 21:32
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3402225

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3402225

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3402225

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3402225

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	1 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	11:37 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 11:37
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	81 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	1 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:25 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 13:25
Temperature (<i>xxx.x</i>)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	72 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3402225

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

1 SEP 2020

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

US3402225

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 1 SEP 2020

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3402225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

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) 1 SEP 2020

What was the treatment time? (00:00-23:59) 12:44 (24 HR)

Treatment Date and Time (derived) 1 SEP 2020 12:44

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

US3402225

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 1 SEP 2020

Collection time (*00:00-23:59*) 12:25 (24 HR)

Collection date and time (derived) 1 SEP 2020 12:25

US3402225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Collection date (<i>dd MMM yyyy</i>)			1 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:27	1 SEP 2020 12:27
Nasopharyngeal Swab 2	No		

US3402225

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.4 °F

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

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

PC Time Stamp 01 SEP 2020 13:20

PC Open Date & Time 01 SEP 2020 13:04

PC Close Date & Time 01 SEP 2020 15:34

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.2 °F

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

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

PC Time Stamp 01 SEP 2020 19:55
PC Open Date & Time 01 SEP 2020 16:29
PC Close Date & Time 02 SEP 2020 11:59

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	02 SEP 2020 21:48
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	03 SEP 2020 20:39
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	04 SEP 2020 20:37
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	06 SEP 2020 09:37
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 6

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	06 SEP 2020 20:53
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

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

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

PC Time Stamp	07 SEP 2020 19:51
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

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

01 SEP 2020 13:20

PC Open Date & Time

01 SEP 2020 13:04

PC Close Date & Time

01 SEP 2020 15:34

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

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

01 SEP 2020 19:55

PC Open Date & Time

01 SEP 2020 16:29

PC Close Date & Time

02 SEP 2020 11:59

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 2

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	02 SEP 2020 21:49
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 3

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	03 SEP 2020 20:40
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:40

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

04 SEP 2020 20:37

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 5

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

06 SEP 2020 09:37

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

06 SEP 2020 20:55

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

07 SEP 2020 19:52

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

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

No

Yes

PC Time stamp	01 SEP 2020 13:21
PC Open Date & Time	01 SEP 2020 13:04
PC Close Date & Time	01 SEP 2020 15:34

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

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

No

Yes

PC Time stamp	01 SEP 2020 19:55
PC Open Date & Time	01 SEP 2020 16:29
PC Close Date & Time	02 SEP 2020 11:59

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:40

	Yes <input type="checkbox"/>
PC Time stamp	02 SEP 2020 21:49
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:40

	Yes <input type="checkbox"/>
PC Time stamp	03 SEP 2020 20:41
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:40

	Yes <input type="checkbox"/>
PC Time stamp	04 SEP 2020 20:38
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:40

	Yes <input type="checkbox"/>
PC Time stamp	06 SEP 2020 09:37
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:40

	Yes <input type="checkbox"/>
PC Time stamp	06 SEP 2020 20:56
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:40

	Yes <input type="checkbox"/>
PC Time stamp	07 SEP 2020 19:52
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3402225

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3402225

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3402225

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 15 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3402225

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3402225

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3402225

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) 29 SEP 2020

Time of assessment (00:00-23:59) 11:13 (24 HR)

Vital Signs Date and Time (derived) 29 SEP 2020 11:13

Temperature (xxx.x) 98.1 F

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) 83 beats/min

Pulse units BPM

Respiratory Rate (xxx) 16 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (xxx) 109 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) 73 mmHg

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

US3402225

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3402225

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 29 SEP 2020

Collection time (*00:00-23:59*) 11:38 (24 HR)

Collection date and time (derived) 29 SEP 2020 11:38

US3402225

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:16:47

Generated On: 09 Jun 2021 17:23:40

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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 04 OCT 2020 22:29:44

Patient Cloud Open Date & Time 04 OCT 2020 00:01

Patient Cloud Close Date & Time 08 OCT 2020 23:59

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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 12 OCT 2020 10:20:03

Patient Cloud Open Date & Time 11 OCT 2020 00:01

Patient Cloud Close Date & Time 15 OCT 2020 23:59

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 OCT 2020 09:02:08
Patient Cloud Open Date & Time	18 OCT 2020 00:01
Patient Cloud Close Date & Time	22 OCT 2020 23:59

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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 09:07:11

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

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

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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 08 NOV 2020 22:20:19

Patient Cloud Open Date & Time 08 NOV 2020 00:01

Patient Cloud Close Date & Time 12 NOV 2020 23:59

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 NOV 2020 14:23:16
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 13:44:05
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 117

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

No

Yes

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

No

Yes

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

Date and time of submission 28 NOV 2020 13:49:08

Patient Cloud Open Date & Time 26 NOV 2020 00:01

Patient Cloud Close Date & Time 30 NOV 2020 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 DEC 2020 13:59:49
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 06:59:57
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 138

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

No

Yes

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

No

Yes

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

Date and time of submission 17 DEC 2020 20:34:38

Patient Cloud Open Date & Time 17 DEC 2020 00:01

Patient Cloud Close Date & Time 21 DEC 2020 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 DEC 2020 07:03:45
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 DEC 2020 15:19:52
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 159

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

No

Yes

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

No

Yes

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

Date and time of submission 07 JAN 2021 08:44:13

Patient Cloud Open Date & Time 07 JAN 2021 00:01

Patient Cloud Close Date & Time 11 JAN 2021 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 JAN 2021 09:10:04
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 173

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

No

Yes

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

No

Yes

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

Date and time of submission 21 JAN 2021 15:26:03

Patient Cloud Open Date & Time 21 JAN 2021 00:01

Patient Cloud Close Date & Time 25 JAN 2021 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 JAN 2021 16:50:42
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	04 FEB 2021 20:47:48
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	11 FEB 2021 05:39:42
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 FEB 2021 16:29:12
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 FEB 2021 15:04:24
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 MAR 2021 17:09:27
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 222

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

No

Yes

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

No

Yes

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

Date and time of submission 12 MAR 2021 10:04:10

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 MAR 2021 19:33:44
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 236

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

No

Yes

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

No

Yes

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

Date and time of submission 25 MAR 2021 20:52:46

Patient Cloud Open Date & Time 25 MAR 2021 00:01

Patient Cloud Close Date & Time 29 MAR 2021 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 APR 2021 12:00:36
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	10 APR 2021 16:42:12
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 APR 2021 14:37:22
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

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

Date and time of submission

26 APR 2021 19:53:49

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 MAY 2021 16:05:18
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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°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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 320

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 341

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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°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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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°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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 404

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

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

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

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

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

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

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 411

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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°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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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°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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 460

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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°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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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°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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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°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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#) 07 FEB 2022 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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°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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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°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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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°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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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°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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#) 06 JUN 2022 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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
Patient Cloud Close Date & Time	20 JUN 2022 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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°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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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°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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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°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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:23:40

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	No	02 MAR 2021 13:39:09

US3402225

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 22:21:19

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 22:21:19

Generated On: 09 Jun 2021 17:23:40

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3402225

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 22:51:12

Generated On: 09 Jun 2021 17:23:40

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 30 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3402225

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:51:12

Generated On: 09 Jun 2021 17:23:40

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3402225

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 22:51:49

Generated On: 09 Jun 2021 17:23:40

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 28 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3402225

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:51:12

Generated On: 09 Jun 2021 17:23:40

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3402225

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 22:51:49

Generated On: 09 Jun 2021 17:23:40

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 26 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3402225

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:51:49

Generated On: 09 Jun 2021 17:23:40

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3402225

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 22:51:49

Generated On: 09 Jun 2021 17:23:40

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 09 MAR 2021

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

Folder OID VISIT4

US3402225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 22:51:49

Generated On: 09 Jun 2021 17:23:40

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) 09 MAR 2021

Time of assessment (00:00-23:59) 14:19 (24 HR)

Vital Signs Date and Time (derived) 09 MAR 2021 14:19

Temperature (xxx.x) 36.7 C

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) 85 beats/min

Pulse units BPM

Respiratory Rate (xxx) 14 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (xxx) 113 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) 66 mmHg

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

US3402225

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 22:51:49

Generated On: 09 Jun 2021 17:23:40

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.

US3402225

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 22:51:49

Generated On: 09 Jun 2021 17:23:40

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 09 MAR 2021

Collection time (*00:00-23:59*) 14:42 (24 HR)

Collection date and time (derived) 09 MAR 2021 14:42

US3402225

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:51:49

Generated On: 09 Jun 2021 17:23:40

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3402225

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 22:51:49

Generated On: 09 Jun 2021 17:23:40

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 31 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3402225

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:51:49

Generated On: 09 Jun 2021 17:23:40

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3402225

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

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 _____

US3402225

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3402225

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:23:40

Generate Next COVID-19 Assessment

Yes

No

US3402225

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

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 18 JAN 2021

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

Folder OID UNBLND_DECIDE

US3402225

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Date of updated informed consent (<i>dd MMM yyyy</i>)	06 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	18 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3402225

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

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

US3402225

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 JAN 2021
Time of assessment (00:00-23:59)	10:00 (24 HR)
Vital Signs Date and Time (derived)	18 JAN 2021 10:00
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3402225

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 JAN 2021
Time of assessment (00:00-23:59)	10:57 (24 HR)
Vital Signs Date and Time (derived)	18 JAN 2021 10:57
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3402225

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

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

18 JAN 2021

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

US3402225

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

Form: Pregnancy Test

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 18 JAN 2021

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3402225

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

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

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

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

What was the treatment date? (dd MMM yyyy) 18 JAN 2021

What was the treatment time? (00:00-23:59) 10:25 (24 HR)

Treatment Date and Time (derived) 18 JAN 2021 10:25

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

US3402225

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 18 JAN 2021

Collection time (*00:00-23:59*) 09:47 (24 HR)

Collection date and time (derived) 18 JAN 2021 09:47

US3402225

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	18 JAN 2021
Collection time (<i>00:00 - 23:59</i>)	09:49
Collection Date and Time (derived)	18 JAN 2021 09:49

US3402225

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

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3402225

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 22:51:49

Generated On: 09 Jun 2021 17:23:40

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 26 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3402225

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:51:49

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 09 MAR 2021

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

Folder OID OLD29

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	09 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	14:19 (24 HR)
Vital Signs Date and Time (derived)	09 MAR 2021 14:19
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	85 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	09 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	15:34 (24 HR)
Vital Signs Date and Time (derived)	09 MAR 2021 15:34
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	73 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3402225

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

09 MAR 2021

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

US3402225

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Was the pregnancy test performed? Yes
No

Date of test (*dd MMM yyyy*) 09 MAR 2021

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3402225

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

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

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

What was the treatment date? (dd MMM yyyy) 09 MAR 2021

What was the treatment time? (00:00-23:59) 15:02 (24 HR)

Treatment Date and Time (derived) 09 MAR 2021 15:02

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

US3402225

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3402225

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 22:51:49

Generated On: 09 Jun 2021 17:23:40

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 17 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3402225

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:51:49

Generated On: 09 Jun 2021 17:23:40

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3402225

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3402225

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Were vital signs assessed? Yes
No

Date of assessment (*dd MMM yyyy*) _____

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

Vital Signs Date and Time (derived) _____

Temperature (*xxx.x*) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (*xxx*) _____

Pulse units _____

Respiratory Rate (*xxx*) _____

Respiratory Rate units _____

Systolic Blood Pressure (*xxx*) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (*xxx*) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3402225

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

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.

US3402225

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	5 APR 2021
Collection time (<i>00:00-23:59</i>)	10:06 (24 HR)
Collection date and time (derived)	5 APR 2021 10:06

US3402225

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Mar 2021 14:40:25

Generated On: 09 Jun 2021 17:23:40

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3402225

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 22:58:18

Generated On: 09 Jun 2021 17:23:40

AEID

Adverse event LEFT UNDERARM SWELLING

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 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes No

If not Ongoing, end date (dd MMM yyyy) 29 SEP 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

US3402225

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 22:58:18

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 22:58:18

Generated On: 09 Jun 2021 17:23:40

AEID USA-US059-2021-MRNA-1273-P30
1000009

Adverse event RUPTURED APPENDIX

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 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

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

End time (00:00-23:59)

AE End Date and Time (derived)

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

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 8 FEB 2021

Hospital Discharge Date (dd MMM yyyy) 16 FEB 2021

Admitted to ICU? Yes
No
Unknown

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 22:58:18

Generated On: 09 Jun 2021 17:23:40

Number of Days in ICU _____

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

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

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure True

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

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

Narrative

US3402225

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 22:58:18

Generated On: 09 Jun 2021 17:23:40

SUBJECT PRESENTED AT
EMERGENCY ROOM WITH
ABDOMINAL PAIN SUBJECT
HAD "ABDOMINAL SCAN" AND
WAS DIAGNOSED WITH AN
OVARIAN CYST. SUBJECT WAS
PRESCRIBED PAIN
MEDICATION AND SENT HOME.
SUBJECT PRESENTED AT
EMERGENCY ROOM 08FEB2021
WITH CONTINUING
ABDOMINAL PAIN. SUBJECT
AGAIN HAD A CT SCAN OF THE
ABDOMEN. SHE WAS
DETERMINED TO HAVE A
RUPTURED APPENDIX.
SUBJECT WAS TAKEN TO
SURGERY WHERE HER
APPENDIX AS WELL AS 5% OF
HER LARGE AND SMALL
INTESTINE WAS REMOVED.
SUBJECT DID HAVE BLOOD
WORK CONSISTING OF A BASIC
METABOLIC PROFILE WITH
THE FOLLOWING ABNORMAL
LABS CRP 3.9, MG/DL NORMAL
RANGE <0.9. MG/DL COMPLETE
BLOOD COUNT WITH
ABNORMAL VALUES OF WHITE
BLOOD COUNT 13.3 NORMAL
4.0-10.5, RED BLOOD COUNT
3.26UL, NORMAL 4.0-5.20,
HEMOGLOBIN 10.0G/DL
NORMAL, 12.2-15.5,
HEMATOCRIT 29.5 NORMAL,

US3402225

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 22:58:18

Generated On: 09 Jun 2021 17:23:40

35.0-47.0. SUBJECT TOLERATED SURGERY WELL. SE WAS GIVEN TYLENOL-CODINE 300-30 MG, LABS DRAWN ON11FEB2021 YIELDED A CRP OF 27.0, A WHITE BLOOD COUNT OF 16.7. AS STATED ABOVE SUBJECT HAS TOLERATED PROCEDURE WELL. SHE HAS BEEN DISCHARGED AND IS DOING THINGS AS TOLERATED.

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

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

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

Yes

No

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

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Name of Medication NORTRIPTYLINE

Prophylaxis Yes
No

Indication MIGRAINES

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 BEDTIME
Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

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

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 1983

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

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Name of Medication TYLENOL-CODEINE

Prophylaxis Yes
No

Indication MIGRAINES

Dose per administration 30/300

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

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

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 1983

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

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Name of Medication ZOLPIDEM

Prophylaxis Yes
No

Indication INSOMNIA

Dose per administration 10

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

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

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) _____ UN UNK 2016

Start date completely unknown _____ False

Ongoing? _____ Yes

_____ 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

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Name of Medication TRAZADONE HCL

Prophylaxis Yes
No

Indication MUSCLE SPASMS

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

BEDTIME

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

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

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) _____ UN UNK 2018

Start date completely unknown _____ False

Ongoing? Yes 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

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Name of Medication HYDROCODONE-ACETAMINOP
HEN

Prophylaxis Yes
No

Indication LEFT SHOULDER PAIN

Dose per administration 5/325

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

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

If route of administration is Other, specify _____

Start date (dd MMM yyyy)	UN MAR 2020
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

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

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Name of Medication MAGNESIUM

Prophylaxis Yes
No

Indication SUPPLEMENT

Dose per administration 3

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

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

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2019

Start date completely unknown False

Ongoing? Yes
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

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Name of Medication MELATONIN

Prophylaxis Yes
No

Indication INSOMNIA

Dose per administration 3

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

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

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) _____ UN UNK 2016

Start date completely unknown _____ False

Ongoing? Yes 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

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Name of Medication MULTIVITAMIN

Prophylaxis Yes
No

Indication SUPPLEMENT

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

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

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2011

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

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes
No

Indication INFLUENZA PROPHYLAXIS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

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

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 28 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 28 OCT 2020

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

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Name of Medication METRANIDAZOLE

Prophylaxis Yes
No

Indication RUPTURED APPENDIX

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

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

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 25 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 08 MAR 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 3

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Name of Medication CIPROFLOXACIN

Prophylaxis Yes
No

Indication RUPTURED APPENDIX

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

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

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 25 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 08 MAR 2021

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

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

Name of Medication BOTOX INJECTIONS

Prophylaxis Yes
No

Indication MIGRAINES

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

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 22:51:11

Generated On: 09 Jun 2021 17:23:40

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

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2019

Start date completely unknown False

Ongoing? Yes
No

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

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 23:32:12

Generated On: 09 Jun 2021 17:23:40

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Apr 2021 23:32:12

Generated On: 09 Jun 2021 17:23:40

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
08 FEB 2021	APPENDECTOMY	Adverse Event	
08 FEB 2021	CT SCAN ABDOMEN	Adverse Event	
25 JAN 2021	CT SCAN ABDOMEN	Adverse Event	
8 FEB 2021	COMPLETE METABOLIC PROFILE	Adverse Event	
8 FEB 2021	C-REACTIVE PROTIEN	Adverse Event	
8 FEB 2021	COMPLETE BLOOD COUNT	Adverse Event	
8 FEB 2021	URINALYSIS	Adverse Event	
8 FEB 2021	LIPASE	Adverse Event	
16 FEB 2021	BASIC METABOLIC PROFILE	Adverse Event	
16 FEB 2021	COMPLETE BLOOD COUNT	Adverse Event	
10 FEB 2021	BASIC METABOLIC PROFILE	Adverse Event	
10 FEB 2021	C REACTIVE PROTIEN	Adverse Event	
10 FEB 2021	COMPLETE BLOOD COUNT	Adverse Event	

US3402225

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:23:40

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

US3402225

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:23:40

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
-

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 03 May 2021 22:58:18

Generated On: 09 Jun 2021 17:23:40

SAEID	USA-US059-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 03 May 2021 22:58:18

Generated On: 09 Jun 2021 17:23:40

SAEID	USA-US059-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	12/FEB/2021 11:00
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.	<input checked="" type="checkbox"/> True

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 03 May 2021 22:58:18

Generated On: 09 Jun 2021 17:23:40

SAEID	USA-US059-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	02/MAR/2021 15:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	<input checked="" type="checkbox"/> True

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Data signed: (b) (4) 03 May 2021 22:58:18

Generated On: 09 Jun 2021 17:23:40

SAEID	USA-US059-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	03/MAR/2021 12:33
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Data signed: (b) (4) 03 May 2021 22:58:18

Generated On: 09 Jun 2021 17:23:40

SAEID	USA-US059-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	04/MAR/2021 11:22
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	<input checked="" type="checkbox"/> True

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form (5)

Data signed: (b) (4) 03 May 2021 22:58:18

Generated On: 09 Jun 2021 17:23:40

SAEID	USA-US059-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	19/APR/2021 13:20
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form (6)

Data signed: (b) (4) 03 May 2021 22:58:18

Generated On: 09 Jun 2021 17:23:40

SAEID	USA-US059-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	30/APR/2021 10:22
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

US3402225 (Prod: Meridian Clinical Research, LLC)

US3402225

Form: Participant Creation

Generated On: 09 Jun 2021 17:23:40

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'US3402225'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 18:14:25

US3402225

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:26:55

US3402225

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '04 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 18:14:26

US3402225

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Clinic (Clinic)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:26:55

US3402225

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'SCRN'	System	05 Aug 2020 12:26:55

US3402225

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:40

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered (b) (6) 1972'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 18:14:27

US3402225

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:40

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '48'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:27:18

US3402225

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:40

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'YEARS'	System	05 Aug 2020 12:27:18

US3402225

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:40

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered '48'	System	04 Aug 2020 19:17:54
User entered empty.	System	04 Aug 2020 19:17:49

US3402225

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:40

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Female (F)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:27:18

US3402225

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:40

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:27:18

US3402225

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:40

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '1'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:27:18

US3402225

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:40

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:27:18

US3402225

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:40

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:27:18

US3402225

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:40

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:27:18

US3402225

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:40

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:27:18

US3402225

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:40

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:27:18

US3402225

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:40

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:27:18

US3402225

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:40

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:27:18

US3402225

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:40

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:27:18

US3402225

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:23:40

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Aug 2020 19:17:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Aug 2020 19:17:54
User entered '4 Aug 2020' reason for change: Data Entry Error	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 19:17:54
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Aug 2020 19:17:49
User entered empty.	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 19:17:49

US3402225

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'Aug 2020'	System	04 Aug 2020 19:17:54
User entered empty.	System	04 Aug 2020 19:17:49

US3402225

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered '2020'	System	04 Aug 2020 19:17:54
User entered empty.	System	04 Aug 2020 19:17:49

US3402225

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:23:40

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Amendment 1 (1)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 19:17:49

US3402225

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 19:17:49

US3402225

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:23:40

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 19:17:49
	(b) (4)	

US3402225

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:23:40

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 19:17:49

US3402225

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:23:40

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 19:17:49

US3402225

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:23:40

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 18:14:26

US3402225

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:23:40

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered '1'	System	04 Aug 2020 19:18:05

US3402225

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 19:18:05
	(b) (4)	

US3402225

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:23:40

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:27:34

US3402225

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:23:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User closed query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please review Childbearing Potential eCRF page, as this information was not noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:34:21
Query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please review Childbearing Potential eCRF page, as this information was not noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify. ' answered with 'PRE MENOPAUSAL' (Site from DM).	Traci Hull (b) (4) (b) (4)	01 Oct 2020 14:47:10
User opened query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please review Childbearing Potential eCRF page, as this information was not noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 21:13:15
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 16:22:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Aug 2020 16:22:03
Data point term sent to Coder	System	05 Aug 2020 16:20:25
Coding entries removed.	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:20:17
User entered 'biLATERAL TUBAL LIGATION' reason for change: Data Entry Error	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:20:17

US3402225

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:23:40

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 12:30:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 12:30:16
Data point term sent to Coder	System	05 Aug 2020 12:28:48
User entered 'TUBAL LIGATION'	Tarin Gordon (b) (4)	05 Aug 2020 12:27:54

US3402225

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'UN Apr 2018'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:27:54

US3402225

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:23:40

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:27:54

US3402225

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:23:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered 'No (N)' reason for change: Data Entry Error	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:28:33
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:27:54

US3402225

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered 'UN Apr 2018' reason for change: Data Entry Error	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:28:33
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:27:54

US3402225

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:23:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:27:54

US3402225

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:23:40

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'Apr 2018'	System	05 Aug 2020 12:27:54

US3402225

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:23:40

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered '2018'	System	05 Aug 2020 12:27:54

US3402225

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'Apr 2018'	System	05 Aug 2020 12:28:33
User entered empty.	System	05 Aug 2020 12:27:54

US3402225

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered '2018'	System	05 Aug 2020 12:28:33
User entered empty.	System	05 Aug 2020 12:27:54

US3402225

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:23:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User closed query 'Per CDM re-query: Response noted, however there is no corresponding record of the associated condition in the Medical History eCRF. Please review and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:27:40
Query 'Per CDM re-query: Response noted, however there is no corresponding record of the associated condition in the Medical History eCRF. Please review and update as appropriate.' answered with 'BREAK THROUGH BLEEDING BETWEEN MENSTRATION CYCLES. BEINGN CANCER CELLS FOUND. BILATERAL TUBAL LIGATION DONE.' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	12 Oct 2020 17:18:01
User opened query 'Per CDM re-query: Response noted, however there is no corresponding record of the associated condition in the Medical History eCRF. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:58:17
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:58:17
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'BREAK THROUGH BLEEDING BETWEEN MENSTRATION CYCLES.' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	08 Oct 2020 15:35:30
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 21:13:29

US3402225

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:23:40

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Endometrial ablation, LLT: Endometrial ablation - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 08:01:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	20 Aug 2020 08:01:19
User entered 'UTERINE ABLASION'	(b) (4)	
	System	05 Aug 2020 12:28:48
	Tarin Gordon (b) (4)	05 Aug 2020 12:28:19
	(b) (4)	

US3402225

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'UN Apr 2018'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:28:19

US3402225

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:23:40

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:28:19

US3402225

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:23:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:28:19
	(b) (4)	

US3402225

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'UN Apr 2018'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:28:19

US3402225

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:23:40

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:28:19

US3402225

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:23:40

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'Apr 2018'	System	05 Aug 2020 12:28:19

US3402225

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:23:40

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered '2018'	System	05 Aug 2020 12:28:19

US3402225

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'Apr 2018'	System	05 Aug 2020 12:28:19

US3402225

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered '2018'	System	05 Aug 2020 12:28:19

US3402225

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:23:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User coded data point as SOC: Nervous system disorders, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	05 Aug 2020 12:30:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Aug 2020 12:30:17
Data point term sent to Coder	System	05 Aug 2020 12:29:49
User entered 'MIGRAINES'	Tarin Gordon (b) (4)	05 Aug 2020 12:29:00
	(b) (4)	

US3402225

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered 'UN UNK 1983'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:29:00

US3402225

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:23:40

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:29:00

US3402225

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:23:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:29:00

US3402225

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:29:00
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:23:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:29:00

US3402225

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:23:40

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'Jan 1983'	System	05 Aug 2020 12:29:00

US3402225

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered '1983'	System	05 Aug 2020 12:29:00

US3402225

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered empty.	System	05 Aug 2020 12:29:00

US3402225

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered empty.	System	05 Aug 2020 12:29:00

US3402225

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:23:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\23.0.	Coder Import (b) (4)	05 Aug 2020 12:30:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Aug 2020 12:30:17
Data point term sent to Coder	System	05 Aug 2020 12:29:49
User entered 'INSOMNIA'	Tarin Gordon (b) (4)	05 Aug 2020 12:29:13

US3402225

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'UN UNK 2016'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:29:13

US3402225

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:23:40

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:29:13
	(b) (4)	

US3402225

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:23:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:29:13

US3402225

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:29:13

US3402225

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:23:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:29:13

US3402225

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:23:40

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'Jan 2016'	System	05 Aug 2020 12:29:13

US3402225

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered '2016'	System	05 Aug 2020 12:29:13

US3402225

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered empty.	System	05 Aug 2020 12:29:13

US3402225

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered empty.	System	05 Aug 2020 12:29:13

US3402225

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:23:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Muscle spasms - version MedDRA\23.0.	Coder Import (b) (4)	24 Nov 2020 12:07:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Nov 2020 12:07:49
User closed query 'Per DM CLR: Please specify the location of MUSCLE SPASMS. Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable. (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 17:33:39
Data point term sent to Coder	System	01 Oct 2020 14:46:33
Query 'Per DM CLR: Please specify the location of MUSCLE SPASMS. Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable. answered with 'DONE' (Site from DM).	Traci Hull (b) (4)	01 Oct 2020 14:46:11
Coding entries removed.	Traci Hull (b) (4)	01 Oct 2020 14:46:05
User entered 'MUSCLE SPASMS LEFT ARM PIT' reason for change: Per Query Resolution	Traci Hull (b) (4)	01 Oct 2020 14:46:05
User opened query 'Per DM CLR: Please specify the location of MUSCLE SPASMS. Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable. (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 21:13:53
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Muscle spasms - version MedDRA\23.0.	Coder Import (b) (4)	05 Aug 2020 12:30:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Aug 2020 12:30:17
Data point term sent to Coder	System	05 Aug 2020 12:29:49

US3402225

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:23:40

[Condition](#)

Audit	User	Time (GMT)
User entered 'MUSCLE SPASMS'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:29:29

US3402225

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered 'UN UNK 2018'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:29:29

US3402225

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:23:40

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:29:29

US3402225

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:23:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:29:29

US3402225

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:29:29

US3402225

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:23:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:29:29

US3402225

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:23:40

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'Jan 2018'	System	05 Aug 2020 12:29:29

US3402225

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:23:40

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered '2018'	System	05 Aug 2020 12:29:29

US3402225

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered empty.	System	05 Aug 2020 12:29:29

US3402225

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered empty.	System	05 Aug 2020 12:29:29

US3402225

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:23:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal pain, LLT: Shoulder pain - version MedDRA\23.0.	Coder Import (b) (4)	05 Aug 2020 12:32:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Aug 2020 12:32:18
Data point term sent to Coder	System	05 Aug 2020 12:30:51
User entered 'LEFT SHOULDER PAIN'	Tarin Gordon (b) (4)	05 Aug 2020 12:29:54

US3402225

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered 'UN Mar 2020'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:29:54

US3402225

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:23:40

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:29:54

US3402225

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:23:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:29:54

US3402225

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:29:54

US3402225

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:23:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:29:54

US3402225

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:23:40

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'Mar 2020'	System	05 Aug 2020 12:29:54

US3402225

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:23:40

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered '2020'	System	05 Aug 2020 12:29:54

US3402225

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered empty.	System	05 Aug 2020 12:29:54

US3402225

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered empty.	System	05 Aug 2020 12:29:54

US3402225

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:23:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\23.0.	Coder Import (b) (4)	05 Aug 2020 12:32:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Aug 2020 12:32:18
Data point term sent to Coder System	System	05 Aug 2020 12:30:51
User entered 'ENVIRONMENTAL ALLERGIES'	Tarin Gordon (b) (4)	05 Aug 2020 12:30:17

US3402225

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'UN UNK 1980'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:30:17

US3402225

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:23:40

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:30:17

US3402225

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:23:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:30:17

US3402225

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:30:17
	(b) (4)	

US3402225

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:23:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:30:17

US3402225

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:23:40

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'Jan 1980'	System	05 Aug 2020 12:30:17

US3402225

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:23:40

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered '1980'	System	05 Aug 2020 12:30:17

US3402225

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered empty.	System	05 Aug 2020 12:30:17

US3402225

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered empty.	System	05 Aug 2020 12:30:17

US3402225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:31:16

US3402225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '4 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:31:16

US3402225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '13:38'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:31:16

US3402225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered '4 Aug 2020 13:38'	System	05 Aug 2020 12:31:16

US3402225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '160.0' cm	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:31:16
DataPoint set to visible.	(b) (4) System	04 Aug 2020 19:18:05

US3402225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '80.4' kg	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:31:16
DataPoint set to visible.	(b) (4) System	04 Aug 2020 19:18:05

US3402225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
Amendment Manager: User entered '31.40625'	System	16 Sep 2020 23:42:50
User entered '31.4'	System	05 Aug 2020 12:31:16
DataPoint set to visible.	System	04 Aug 2020 19:18:05

US3402225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'kg/m2'	System	05 Aug 2020 12:31:16
DataPoint set to visible.	System	04 Aug 2020 19:18:05

US3402225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 16:44:47
User entered '36.4' C	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:31:16

US3402225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 16:44:47
User entered 'Oral (Oral)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:31:16

US3402225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:31:16

US3402225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 16:44:47
User entered '82'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:31:16

US3402225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'bpm'	System	05 Aug 2020 12:31:16

US3402225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 16:44:47
User entered '16'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:31:16

US3402225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'breaths/min'	System	05 Aug 2020 12:31:16

US3402225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 16:44:47
User entered '118'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:31:16

US3402225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'mmHg'	System	05 Aug 2020 12:31:16

US3402225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 16:44:47
User entered '68'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:31:16

US3402225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'mmHg'	System	05 Aug 2020 12:31:16

US3402225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35

US3402225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35

US3402225

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:31:38

US3402225

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	06 Sep 2020 12:41:03
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	01 Sep 2020 17:39:17
User entered '4 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:31:38

US3402225

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:23:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '4 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:32:01
	(b) (4)	

US3402225

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:23:40

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:32:01

US3402225

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:23:40

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:32:01

US3402225

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:23:40

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:32:01
	(b) (4)	

US3402225

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:32:01

US3402225

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:23:40

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:32:01

US3402225

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:32:01
	(b) (4)	

US3402225

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:23:40

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:32:01

US3402225

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:32:13

US3402225

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '4 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:32:13

US3402225

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered 'Urine (URINE)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:32:13

US3402225

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Negative (NEGATIVE)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:32:13

US3402225

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:32:13

US3402225

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:32:13

US3402225

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:32:13

US3402225

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered empty.	System	05 Aug 2020 12:32:13

US3402225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:32:43
	(b) (4)	

US3402225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:32:43

US3402225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:32:43

US3402225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:32:43
	(b) (4)	

US3402225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:40

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:32:43

US3402225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:32:43
	(b) (4)	

US3402225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:32:43
	(b) (4)	

US3402225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:32:43
	(b) (4)	

US3402225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:32:43

US3402225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:32:43
	(b) (4)	

US3402225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:32:43
	(b) (4)	

US3402225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:40

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:32:43
	(b) (4)	

US3402225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:40

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:32:43

US3402225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:40

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:32:43

US3402225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:40

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '0'	(b) (4) Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:32:43

US3402225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:32:43

US3402225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:32:43

US3402225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:32:43

US3402225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '1'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:32:43

US3402225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:40

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:32:43

US3402225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:40

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:32:43

US3402225

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:33:05

US3402225

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '4 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:33:05

US3402225

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Clinic (Clinic)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:33:05

US3402225

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'VISIT1'	System	05 Aug 2020 12:33:05

US3402225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '04 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 18:14:34

US3402225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:23:40

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 02:01:58
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:01:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Aug 2020 18:14:34
User entered '100968' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 18:14:34

US3402225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 18:14:34

US3402225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:33:29
	(b) (4)	

US3402225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:33:29
	(b) (4)	

US3402225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:33:29

US3402225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:23:40

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:33:29
	(b) (4)	

US3402225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:23:40

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:33:29

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:40

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 16:44:25
User entered '160.0' cm	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:40

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 16:44:25
User entered '80.4' kg	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:40

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 16:44:25
User entered '160.0' cm	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:40

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 16:44:25
User entered '80.4' kg	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User accepted default value 'Pre-Dose (PREDOSE)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '4 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:34:46
	(b) (4)	

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '13:38'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered '4 Aug 2020 13:38'	System	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '36.4' C	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Oral (Oral)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:34:46
	(b) (4)	

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:34:46
	(b) (4)	

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '82'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'bpm'	System	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '16'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'breaths/min'	System	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '118'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'mmHg'	System	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '68'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'mmHg'	System	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:40

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 16:44:25
User entered '160.0' cm	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:40

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 16:44:25
User entered '80.4' kg	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User accepted default value 'Post-Dose (POSTDOSE)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '4 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:34:46
	(b) (4)	

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	17 Aug 2020 19:29:27
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 MIN' (Site from System).	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:34:55
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).	System	05 Aug 2020 12:34:46
User entered '15:30'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered '4 Aug 2020 15:30'	System	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '36.9' C	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered 'Oral (Oral)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '82'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'bpm'	System	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '16'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'breaths/min'	System	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered '117'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'mmHg'	System	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	18 Sep 2020 19:10:32
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	18 Sep 2020 19:10:32
User entered '70' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	18 Sep 2020 19:10:32
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:42:50
User entered '7'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'mmHg'	System	05 Aug 2020 12:34:46

US3402225

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:40

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:35:05

US3402225

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '4 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:35:05
	(b) (4)	

US3402225

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User closed query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:05:37
Query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	06 Oct 2020 11:43:06
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	06 Oct 2020 11:43:02
User opened query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 08:46:44
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:35:17

US3402225

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	06 Oct 2020 11:43:02
User entered '4 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:35:17

US3402225

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	06 Oct 2020 11:43:02
User entered 'Urine (URINE)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:35:17

US3402225

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	06 Oct 2020 11:43:02
User entered 'Negative (NEGATIVE)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:35:17

US3402225

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User closed query 'Per CDM: Please provide a response for Was FSH sample collected?' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 05:00:36
Query 'Per CDM: Please provide a response for Was FSH sample collected?' answered with 'UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	19 Mar 2021 18:37:10
Signature has been broken.	Tammy Kohn (b) (4) (b) (4)	19 Mar 2021 18:37:04
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	19 Mar 2021 18:37:04
User opened query 'Per CDM: Please provide a response for Was FSH sample collected?' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 18:36:53
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	06 Oct 2020 11:43:02
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:35:17

US3402225

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:35:17

US3402225

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:35:17

US3402225

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered empty.	System	05 Aug 2020 12:35:17

US3402225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 19:18:39

US3402225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 19:18:39
	(b) (4)	

US3402225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 19:18:39
	(b) (4)	

US3402225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'MRNA-1273 OR PLACEBO'	System	04 Aug 2020 19:18:39

US3402225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '4 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 19:18:39
	(b) (4)	

US3402225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '14:52'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 19:18:39

US3402225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered '4 Aug 2020 14:52'	System	04 Aug 2020 19:18:39

US3402225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Left Arm (LEFT ARM)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 19:18:39

US3402225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'ONCE'	System	04 Aug 2020 19:18:39

US3402225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'INTRAMUSCULAR'	System	04 Aug 2020 19:18:39

US3402225

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:35:38

US3402225

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '4 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:35:38
	(b) (4)	

US3402225

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '14:26'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:35:38
	(b) (4)	

US3402225

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered '4 Aug 2020 14:26'	System	05 Aug 2020 12:35:38

US3402225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:23:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '4 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:35:53

US3402225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:23:40

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:35:53

US3402225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:23:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:35:53

US3402225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:23:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:16:48
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	05 Aug 2020 12:36:07
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	05 Aug 2020 12:36:07
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Aug 2020 12:36:07
User entered '14:23' reason for change: Data Entry Error	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:36:07
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Aug 2020 12:35:53
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	05 Aug 2020 12:35:53
User entered '14:2' (non-conformant).	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:35:53

US3402225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered '4 Aug 2020 14:23'	System	05 Aug 2020 12:36:07
User entered '4 Aug 2020 14:2' (non-conformant).	System	05 Aug 2020 12:35:53

US3402225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:23:40

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:35:53

US3402225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:23:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:35:53

US3402225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:23:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:35:53

US3402225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered empty.	System	05 Aug 2020 12:35:53

US3402225

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:36:14

US3402225

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered '1'	System	05 Aug 2020 12:36:14

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T15:34:16', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '1fc6eb61-0e4c-4cbb-8945-716ba0eff618' User entered 'Yes (Y)'	System	04 Aug 2020 19:36:50
	System	04 Aug 2020 19:36:50

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T15:34:22', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '1fc6eb61-0e4c-4cbb-8945-716ba0eff618' User entered '98.4'	System	04 Aug 2020 19:36:50
	System	04 Aug 2020 19:36:50

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T15:34:31', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '1fc6eb61-0e4c-4cbb-8945-716ba0eff618'	System	04 Aug 2020 19:36:50
User entered 'No (N)'	System	04 Aug 2020 19:36:50

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T15:36:46', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '1fc6eb61-0e4c-4cbb-8945-716ba0eff618' User entered '04 Aug 2020 15:36'	System	04 Aug 2020 19:36:50
	System	04 Aug 2020 19:36:50

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '04 Aug 2020 15:12'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '04 Aug 2020 17:42'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T19:48:47', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'fa0d0f32-3225-4a16-aed2-7ec9096b33ce' User entered 'Yes (Y)'	System	04 Aug 2020 23:49:07
	System	04 Aug 2020 23:49:07

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T19:48:53', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'fa0d0f32-3225-4a16-aed2-7ec9096b33ce' User entered '98.0'	System	04 Aug 2020 23:49:07
	System	04 Aug 2020 23:49:07

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T19:48:58', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'fa0d0f32-3225-4a16-aed2-7ec9096b33ce'	System	04 Aug 2020 23:49:07
User entered 'No (N)'	System	04 Aug 2020 23:49:07

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T19:49:05', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'fa0d0f32-3225-4a16-aed2-7ec9096b33ce' User entered '04 Aug 2020 19:49'	System	04 Aug 2020 23:49:07
	System	04 Aug 2020 23:49:07

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '04 Aug 2020 18:37'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 2'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-05T18:38:47', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '66a955d7-1962-4562-a933-6c7312eaedee' User entered 'Yes (Y)'	System	05 Aug 2020 22:39:04
	System	05 Aug 2020 22:39:04

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-05T18:38:52', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '66a955d7-1962-4562-a933-6c7312eaedee' User entered '98.0'	System	05 Aug 2020 22:39:04
	System	05 Aug 2020 22:39:04

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-05T18:38:57', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '66a955d7-1962-4562-a933-6c7312eaedee'	System	05 Aug 2020 22:39:04
User entered 'No (N)'	System	05 Aug 2020 22:39:04

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-05T18:39:02', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '66a955d7-1962-4562-a933-6c7312eaedee' User entered '05 Aug 2020 18:39'	System	05 Aug 2020 22:39:04
	System	05 Aug 2020 22:39:04

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 3'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-06T19:20:34', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'c331ae39-b2dc-4e05-ace7-108f4b9c9df6' User entered 'Yes (Y)'	System	06 Aug 2020 23:20:51
	System	06 Aug 2020 23:20:51

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-06T19:20:40', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'c331ae39-b2dc-4e05-ace7-108f4b9c9df6' User entered '97.5'	System	06 Aug 2020 23:20:51
	System	06 Aug 2020 23:20:51

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-06T19:20:43', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'c331ae39-b2dc-4e05-ace7-108f4b9c9df6'	System	06 Aug 2020 23:20:51
User entered 'No (N)'	System	06 Aug 2020 23:20:51

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-06T19:20:49', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'c331ae39-b2dc-4e05-ace7-108f4b9c9df6' User entered '06 Aug 2020 19:20'	System	06 Aug 2020 23:20:51
	System	06 Aug 2020 23:20:51

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 4'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-07T22:52:09', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'ea263166-95b5-4c83-94ff-cb886ac72408' User entered 'Yes (Y)'	System	08 Aug 2020 02:52:45
	System	08 Aug 2020 02:52:45

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-07T22:52:35', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'ea263166-95b5-4c83-94ff-cb886ac72408' User entered '97.9'	System	08 Aug 2020 02:52:45
	System	08 Aug 2020 02:52:45

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-07T22:52:38', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'ea263166-95b5-4c83-94ff-cb886ac72408'	System	08 Aug 2020 02:52:45
User entered 'No (N)'	System	08 Aug 2020 02:52:45

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-07T22:52:42', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'ea263166-95b5-4c83-94ff-cb886ac72408' User entered '07 Aug 2020 22:52'	System	08 Aug 2020 02:52:45
	System	08 Aug 2020 02:52:45

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 5'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-08T22:59:11', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '01f06d5d-1a3e-4b82-93fd-d764624a7a74' User entered 'Yes (Y)'	System	09 Aug 2020 02:59:26
	System	09 Aug 2020 02:59:26

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-08T22:59:18', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '01f06d5d-1a3e-4b82-93fd-d764624a7a74' User entered '97.5'	System	09 Aug 2020 02:59:26
	System	09 Aug 2020 02:59:26

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-08T22:59:20', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '01f06d5d-1a3e-4b82-93fd-d764624a7a74' User entered 'No (N)'	System	09 Aug 2020 02:59:26
	System	09 Aug 2020 02:59:26

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-08T22:59:24', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '01f06d5d-1a3e-4b82-93fd-d764624a7a74' User entered '08 Aug 2020 22:59'	System	09 Aug 2020 02:59:26
	System	09 Aug 2020 02:59:26

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 6'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-09T19:42:22', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '12e8a736-747a-4f12-9575-9763d5f7e52b' User entered 'Yes (Y)'	System	09 Aug 2020 23:42:37
	System	09 Aug 2020 23:42:37

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-09T19:42:29', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '12e8a736-747a-4f12-9575-9763d5f7e52b' User entered '98.1'	System	09 Aug 2020 23:42:37
	System	09 Aug 2020 23:42:37

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-09T19:42:31', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '12e8a736-747a-4f12-9575-9763d5f7e52b'	System	09 Aug 2020 23:42:37
User entered 'No (N)'	System	09 Aug 2020 23:42:37

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-09T19:42:34', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '12e8a736-747a-4f12-9575-9763d5f7e52b' User entered '09 Aug 2020 19:42'	System	09 Aug 2020 23:42:37
	System	09 Aug 2020 23:42:37

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 7'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-10T21:30:43', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'dbec5bf2-31b4-4d23-a49c-f3566320e9ac' User entered 'Yes (Y)'	System	11 Aug 2020 01:31:06
	System	11 Aug 2020 01:31:06

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-10T21:30:51', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'dbec5bf2-31b4-4d23-a49c-f3566320e9ac' User entered '98.2'	System	11 Aug 2020 01:31:06
	System	11 Aug 2020 01:31:06

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-10T21:30:54', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'dbec5bf2-31b4-4d23-a49c-f3566320e9ac' User entered 'No (N)'	System	11 Aug 2020 01:31:06
	System	11 Aug 2020 01:31:06

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-10T21:31:02', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'dbec5bf2-31b4-4d23-a49c-f3566320e9ac' User entered '10 Aug 2020 21:31'	System	11 Aug 2020 01:31:06
	System	11 Aug 2020 01:31:06

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T15:39:41', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '63c010a2-76ff-42cf-8817-066463303fac'	System	04 Aug 2020 19:40:00
User entered 'Does not interfere with activity (2)'	System	04 Aug 2020 19:40:00

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T15:39:43', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '63c010a2-76ff-42cf-8817-066463303fac'	System	04 Aug 2020 19:40:00
User entered 'No (N)'	System	04 Aug 2020 19:40:00

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T15:39:47', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '63c010a2-76ff-42cf-8817-066463303fac' User entered 'No (N)'	System	04 Aug 2020 19:40:00
	System	04 Aug 2020 19:40:00

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T15:39:51', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '63c010a2-76ff-42cf-8817-066463303fac'	System	04 Aug 2020 19:40:00
User entered 'None (1)'	System	04 Aug 2020 19:40:00

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T15:39:57', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '63c010a2-76ff-42cf-8817-066463303fac' User entered '04 Aug 2020 15:39'	System	04 Aug 2020 19:40:00
	System	04 Aug 2020 19:40:00

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '04 Aug 2020 15:12'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '04 Aug 2020 17:42'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T19:49:12', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '4f166d2c-d5d6-4976-825b-b0a6212d04bf'	System	04 Aug 2020 23:49:42
User entered 'None (1)'	System	04 Aug 2020 23:49:42

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T19:49:17', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '4f166d2c-d5d6-4976-825b-b0a6212d04bf'	System	04 Aug 2020 23:49:42
User entered 'No (N)'	System	04 Aug 2020 23:49:42

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T19:49:30', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '4f166d2c-d5d6-4976-825b-b0a6212d04bf' User entered 'No (N)'	System	04 Aug 2020 23:49:42
	System	04 Aug 2020 23:49:42

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T19:49:34', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '4f166d2c-d5d6-4976-825b-b0a6212d04bf'	System	04 Aug 2020 23:49:42
User entered 'None (1)'	System	04 Aug 2020 23:49:42

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T19:49:39', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '4f166d2c-d5d6-4976-825b-b0a6212d04bf' User entered '04 Aug 2020 19:49'	System	04 Aug 2020 23:49:42
	System	04 Aug 2020 23:49:42

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '04 Aug 2020 18:37'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 2'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-05T18:39:08', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'b28cc838-8291-4416-bab2-53cff49c3a6e'	System	05 Aug 2020 22:39:28
User entered 'None (1)'	System	05 Aug 2020 22:39:28

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-05T18:39:11', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'b28cc838-8291-4416-bab2-53cff49c3a6e'	System	05 Aug 2020 22:39:28
User entered 'No (N)'	System	05 Aug 2020 22:39:28

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-05T18:39:15', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'b28cc838-8291-4416-bab2-53cff49c3a6e'	System	05 Aug 2020 22:39:28
User entered 'No (N)'	System	05 Aug 2020 22:39:28

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-05T18:39:21', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'b28cc838-8291-4416-bab2-53cff49c3a6e'	System	05 Aug 2020 22:39:28
User entered 'None (1)'	System	05 Aug 2020 22:39:28

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-05T18:39:26', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'b28cc838-8291-4416-bab2-53cff49c3a6e' User entered '05 Aug 2020 18:39'	System	05 Aug 2020 22:39:28
	System	05 Aug 2020 22:39:28

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 3'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-06T19:20:54', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'e928d1b0-3383-41ec-8646-5ff68babb48b' User entered 'None (1)'	System	06 Aug 2020 23:21:13
	System	06 Aug 2020 23:21:13

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-06T19:20:59', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'e928d1b0-3383-41ec-8646-5ff68babb48b' User entered 'No (N)'	System	06 Aug 2020 23:21:13
	System	06 Aug 2020 23:21:13

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-06T19:21:02', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'e928d1b0-3383-41ec-8646-5ff68babb48b' User entered 'No (N)'	System	06 Aug 2020 23:21:13
	System	06 Aug 2020 23:21:13

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-06T19:21:05', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'e928d1b0-3383-41ec-8646-5ff68babb48b' User entered 'None (1)'	System	06 Aug 2020 23:21:13
	System	06 Aug 2020 23:21:13

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-06T19:21:09', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'e928d1b0-3383-41ec-8646-5ff68babb48b' User entered '06 Aug 2020 19:21'	System	06 Aug 2020 23:21:13
	System	06 Aug 2020 23:21:13

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 4'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-07T22:52:46', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '37e88dd1-ed6b-4f97-ac4a-ef388a3b6423'	System	08 Aug 2020 02:53:07
User entered 'None (1)'	System	08 Aug 2020 02:53:07

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-07T22:52:49', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '37e88dd1-ed6b-4f97-ac4a-ef388a3b6423' User entered 'No (N)'	System	08 Aug 2020 02:53:07
	System	08 Aug 2020 02:53:07

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-07T22:52:50', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '37e88dd1-ed6b-4f97-ac4a-ef388a3b6423'	System	08 Aug 2020 02:53:07
User entered 'No (N)'	System	08 Aug 2020 02:53:07

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-07T22:52:56', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '37e88dd1-ed6b-4f97-ac4a-ef388a3b6423'	System	08 Aug 2020 02:53:07
User entered 'None (1)'	System	08 Aug 2020 02:53:07

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-07T22:53:05', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '37e88dd1-ed6b-4f97-ac4a-ef388a3b6423' User entered '07 Aug 2020 22:53'	System	08 Aug 2020 02:53:07
	System	08 Aug 2020 02:53:07

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 5'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-08T22:59:29', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'ee2216bb-a595-461e-8abd-71168c066d10' User entered 'None (1)'	System	09 Aug 2020 02:59:43
	System	09 Aug 2020 02:59:43

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-08T22:59:31', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'ee2216bb-a595-461e-8abd-71168c066d10' User entered 'No (N)'	System	09 Aug 2020 02:59:43
	System	09 Aug 2020 02:59:43

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-08T22:59:33', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'ee2216bb-a595-461e-8abd-71168c066d10' User entered 'No (N)'	System	09 Aug 2020 02:59:43
	System	09 Aug 2020 02:59:43

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-08T22:59:36', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'ee2216bb-a595-461e-8abd-71168c066d10'	System	09 Aug 2020 02:59:43
User entered 'None (1)'	System	09 Aug 2020 02:59:43

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-08T22:59:40', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'ee2216bb-a595-461e-8abd-71168c066d10' User entered '08 Aug 2020 22:59'	System	09 Aug 2020 02:59:43
	System	09 Aug 2020 02:59:43

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 6'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-09T19:42:40', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '248f9401-fc08-46a2-90d6-9a6cac8b23f7'	System	09 Aug 2020 23:42:53
User entered 'None (1)'	System	09 Aug 2020 23:42:53

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-09T19:42:42', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '248f9401-fc08-46a2-90d6-9a6cac8b23f7'	System	09 Aug 2020 23:42:53
User entered 'No (N)'	System	09 Aug 2020 23:42:53

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-09T19:42:44', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '248f9401-fc08-46a2-90d6-9a6cac8b23f7'	System	09 Aug 2020 23:42:53
User entered 'No (N)'	System	09 Aug 2020 23:42:53

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-09T19:42:46', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '248f9401-fc08-46a2-90d6-9a6cac8b23f7'	System	09 Aug 2020 23:42:53
User entered 'None (1)'	System	09 Aug 2020 23:42:53

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-09T19:42:49', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '248f9401-fc08-46a2-90d6-9a6cac8b23f7' User entered '09 Aug 2020 19:42'	System	09 Aug 2020 23:42:53
	System	09 Aug 2020 23:42:53

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 7'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-10T21:31:07', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '8fb9a2be-a604-4663-869a-bbe41671e311'	System	11 Aug 2020 01:31:31
User entered 'None (1)'	System	11 Aug 2020 01:31:31

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-10T21:31:11', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '8fb9a2be-a604-4663-869a-bbe41671e311' User entered 'No (N)'	System	11 Aug 2020 01:31:31
	System	11 Aug 2020 01:31:31

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-10T21:31:14', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '8fb9a2be-a604-4663-869a-bbe41671e311' User entered 'No (N)'	System	11 Aug 2020 01:31:31
	System	11 Aug 2020 01:31:31

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-10T21:31:16', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '8fb9a2be-a604-4663-869a-bbe41671e311'	System	11 Aug 2020 01:31:31
User entered 'None (1)'	System	11 Aug 2020 01:31:31

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-10T21:31:28', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '8fb9a2be-a604-4663-869a-bbe41671e311' User entered '10 Aug 2020 21:31'	System	11 Aug 2020 01:31:31
	System	11 Aug 2020 01:31:31

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T15:40:06', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'd1b91b9a-b7b4-4bd2-be98-bc9dae4e1775' User entered 'None (0)'	System	04 Aug 2020 19:40:43
	System	04 Aug 2020 19:40:43

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T15:40:10', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'd1b91b9a-b7b4-4bd2-be98-bc9dae4e1775' User entered 'None (0)'	System	04 Aug 2020 19:40:43
	System	04 Aug 2020 19:40:43

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T15:40:22', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'd1b91b9a-b7b4-4bd2-be98-bc9dae4e1775' User entered 'None (0)'	System	04 Aug 2020 19:40:43
	System	04 Aug 2020 19:40:43

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T15:40:26', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'd1b91b9a-b7b4-4bd2-be98-bc9dae4e1775' User entered 'None (0)'	System	04 Aug 2020 19:40:43
	System	04 Aug 2020 19:40:43

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T15:40:28', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'd1b91b9a-b7b4-4bd2-be98-bc9dae4e1775' User entered 'None (0)'	System	04 Aug 2020 19:40:43
	System	04 Aug 2020 19:40:43

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T15:40:30', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'd1b91b9a-b7b4-4bd2-be98-bc9dae4e1775' User entered 'None (0)'	System	04 Aug 2020 19:40:43
	System	04 Aug 2020 19:40:43

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T15:40:37', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'd1b91b9a-b7b4-4bd2-be98-bc9dae4e1775' User entered 'No (N)'	System	04 Aug 2020 19:40:43
	System	04 Aug 2020 19:40:43

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T15:40:41', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'd1b91b9a-b7b4-4bd2-be98-bc9dae4e1775' User entered '04 Aug 2020 15:40'	System	04 Aug 2020 19:40:43
	System	04 Aug 2020 19:40:43

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '04 Aug 2020 15:12'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '04 Aug 2020 17:42'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T19:49:44', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '86abf008-35ea-4825-a599-462fefcf82b1' User entered 'None (0)'	System	04 Aug 2020 23:50:20
	System	04 Aug 2020 23:50:20

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T19:49:47', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '86abf008-35ea-4825-a599-462fefcf82b1' User entered 'None (0)'	System	04 Aug 2020 23:50:20
	System	04 Aug 2020 23:50:20

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T19:49:49', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '86abf008-35ea-4825-a599-462fefcf82b1' User entered 'None (0)'	System	04 Aug 2020 23:50:20
	System	04 Aug 2020 23:50:20

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T19:49:54', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '86abf008-35ea-4825-a599-462fefcf82b1' User entered 'None (0)'	System	04 Aug 2020 23:50:20
	System	04 Aug 2020 23:50:20

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T19:49:57', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '86abf008-35ea-4825-a599-462fefcf82b1' User entered 'None (0)'	System	04 Aug 2020 23:50:20
	System	04 Aug 2020 23:50:20

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T19:49:59', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '86abf008-35ea-4825-a599-462fefcf82b1' User entered 'None (0)'	System	04 Aug 2020 23:50:20
	System	04 Aug 2020 23:50:20

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T19:50:16', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '86abf008-35ea-4825-a599-462fefcf82b1' User entered 'No (N)'	System	04 Aug 2020 23:50:20
	System	04 Aug 2020 23:50:20

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-04T19:50:19', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '86abf008-35ea-4825-a599-462fefcf82b1' User entered '04 Aug 2020 19:50'	System	04 Aug 2020 23:50:20
	System	04 Aug 2020 23:50:20

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '04 Aug 2020 18:37'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 2'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-05T18:39:31', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '98f2e8a5-574c-4453-9a95-210296818be7' User entered 'None (0)'	System	05 Aug 2020 22:39:53
	System	05 Aug 2020 22:39:53

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-05T18:39:32', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '98f2e8a5-574c-4453-9a95-210296818be7' User entered 'None (0)'	System	05 Aug 2020 22:39:53
	System	05 Aug 2020 22:39:53

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-05T18:39:34', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '98f2e8a5-574c-4453-9a95-210296818be7' User entered 'None (0)'	System	05 Aug 2020 22:39:53
	System	05 Aug 2020 22:39:53

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-05T18:39:36', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '98f2e8a5-574c-4453-9a95-210296818be7' User entered 'None (0)'	System	05 Aug 2020 22:39:53
	System	05 Aug 2020 22:39:53

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-05T18:39:37', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '98f2e8a5-574c-4453-9a95-210296818be7' User entered 'None (0)'	System	05 Aug 2020 22:39:53
	System	05 Aug 2020 22:39:53

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-05T18:39:40', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '98f2e8a5-574c-4453-9a95-210296818be7' User entered 'None (0)'	System	05 Aug 2020 22:39:53
	System	05 Aug 2020 22:39:53

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-05T18:39:43', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '98f2e8a5-574c-4453-9a95-210296818be7'	System	05 Aug 2020 22:39:53
User entered 'No (N)'	System	05 Aug 2020 22:39:53

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-05T18:39:51', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '98f2e8a5-574c-4453-9a95-210296818be7' User entered '05 Aug 2020 18:39'	System	05 Aug 2020 22:39:53
	System	05 Aug 2020 22:39:53

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 3'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-06T19:21:15', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '3cc695f6-9ee3-4db3-b90c-2424996779ed' User entered 'None (0)'	System	06 Aug 2020 23:21:35
	System	06 Aug 2020 23:21:35

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-06T19:21:17', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '3cc695f6-9ee3-4db3-b90c-2424996779ed' User entered 'None (0)'	System	06 Aug 2020 23:21:35
	System	06 Aug 2020 23:21:35

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-06T19:21:18', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '3cc695f6-9ee3-4db3-b90c-2424996779ed' User entered 'None (0)'	System	06 Aug 2020 23:21:35
	System	06 Aug 2020 23:21:35

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-06T19:21:20', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '3cc695f6-9ee3-4db3-b90c-2424996779ed' User entered 'None (0)'	System	06 Aug 2020 23:21:35
	System	06 Aug 2020 23:21:35

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-06T19:21:22', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '3cc695f6-9ee3-4db3-b90c-2424996779ed' User entered 'None (0)'	System	06 Aug 2020 23:21:35
	System	06 Aug 2020 23:21:35

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-06T19:21:24', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '3cc695f6-9ee3-4db3-b90c-2424996779ed' User entered 'None (0)'	System	06 Aug 2020 23:21:35
	System	06 Aug 2020 23:21:35

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-06T19:21:27', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '3cc695f6-9ee3-4db3-b90c-2424996779ed' User entered 'No (N)'	System	06 Aug 2020 23:21:35
	System	06 Aug 2020 23:21:35

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-06T19:21:32', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '3cc695f6-9ee3-4db3-b90c-2424996779ed' User entered '06 Aug 2020 19:21'	System	06 Aug 2020 23:21:35
	System	06 Aug 2020 23:21:35

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 4'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-07T22:53:13', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '7040bf21-bd12-40ce-822f-e35fe89a84c4' User entered 'None (0)'	System	08 Aug 2020 02:53:43
	System	08 Aug 2020 02:53:43

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-07T22:53:15', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '7040bf21-bd12-40ce-822f-e35fe89a84c4' User entered 'None (0)'	System	08 Aug 2020 02:53:43
	System	08 Aug 2020 02:53:43

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-07T22:53:17', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '7040bf21-bd12-40ce-822f-e35fe89a84c4'	System	08 Aug 2020 02:53:43
User entered 'None (0)'	System	08 Aug 2020 02:53:43

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-07T22:53:19', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '7040bf21-bd12-40ce-822f-e35fe89a84c4' User entered 'None (0)'	System	08 Aug 2020 02:53:43
	System	08 Aug 2020 02:53:43

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-07T22:53:21', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '7040bf21-bd12-40ce-822f-e35fe89a84c4' User entered 'None (0)'	System	08 Aug 2020 02:53:43
	System	08 Aug 2020 02:53:43

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-07T22:53:26', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '7040bf21-bd12-40ce-822f-e35fe89a84c4' User entered 'None (0)'	System	08 Aug 2020 02:53:43
	System	08 Aug 2020 02:53:43

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-07T22:53:28', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '7040bf21-bd12-40ce-822f-e35fe89a84c4'	System	08 Aug 2020 02:53:43
User entered 'No (N)'	System	08 Aug 2020 02:53:43

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-07T22:53:40', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '7040bf21-bd12-40ce-822f-e35fe89a84c4' User entered '07 Aug 2020 22:53'	System	08 Aug 2020 02:53:43
	System	08 Aug 2020 02:53:43

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 5'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-08T22:59:44', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '76363974-a7cf-4dc9-9875-7fc466cfc107' User entered 'None (0)'	System	09 Aug 2020 03:00:10
	System	09 Aug 2020 03:00:10

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-08T22:59:46', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '76363974-a7cf-4dc9-9875-7fc466cfc107' User entered 'None (0)'	System	09 Aug 2020 03:00:10
	System	09 Aug 2020 03:00:10

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-08T22:59:49', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '76363974-a7cf-4dc9-9875-7fc466cfc107'	System	09 Aug 2020 03:00:10
User entered 'None (0)'	System	09 Aug 2020 03:00:10

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-08T22:59:51', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '76363974-a7cf-4dc9-9875-7fc466cfc107'	System	09 Aug 2020 03:00:10
User entered 'None (0)'	System	09 Aug 2020 03:00:10

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-08T22:59:53', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '76363974-a7cf-4dc9-9875-7fc466cfc107' User entered 'None (0)'	System	09 Aug 2020 03:00:10
	System	09 Aug 2020 03:00:10

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-08T22:59:56', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '76363974-a7cf-4dc9-9875-7fc466cfc107'	System	09 Aug 2020 03:00:10
User entered 'None (0)'	System	09 Aug 2020 03:00:10

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-08T22:59:59', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '76363974-a7cf-4dc9-9875-7fc466cfc107'	System	09 Aug 2020 03:00:10
User entered 'No (N)'	System	09 Aug 2020 03:00:10

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-08T23:00:06', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '76363974-a7cf-4dc9-9875-7fc466cfc107'	System	09 Aug 2020 03:00:10
User entered '08 Aug 2020 23:00'	System	09 Aug 2020 03:00:10

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 6'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-09T19:42:53', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'e426b588-b043-44ac-b42b-e8086d3e14b9'	System	09 Aug 2020 23:43:10
User entered 'None (0)'	System	09 Aug 2020 23:43:10

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-09T19:42:55', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'e426b588-b043-44ac-b42b-e8086d3e14b9' User entered 'None (0)'	System	09 Aug 2020 23:43:10
	System	09 Aug 2020 23:43:10

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-09T19:42:56', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'e426b588-b043-44ac-b42b-e8086d3e14b9' User entered 'None (0)'	System	09 Aug 2020 23:43:10
	System	09 Aug 2020 23:43:10

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-09T19:42:58', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'e426b588-b043-44ac-b42b-e8086d3e14b9' User entered 'None (0)'	System	09 Aug 2020 23:43:10
	System	09 Aug 2020 23:43:10

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-09T19:42:59', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'e426b588-b043-44ac-b42b-e8086d3e14b9' User entered 'None (0)'	System	09 Aug 2020 23:43:10
	System	09 Aug 2020 23:43:10

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-09T19:43:02', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'e426b588-b043-44ac-b42b-e8086d3e14b9' User entered 'None (0)'	System	09 Aug 2020 23:43:10
	System	09 Aug 2020 23:43:10

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-09T19:43:04', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'e426b588-b043-44ac-b42b-e8086d3e14b9'	System	09 Aug 2020 23:43:10
User entered 'No (N)'	System	09 Aug 2020 23:43:10

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-09T19:43:08', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'e426b588-b043-44ac-b42b-e8086d3e14b9' User entered '09 Aug 2020 19:43'	System	09 Aug 2020 23:43:10
	System	09 Aug 2020 23:43:10

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 7'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-10T21:31:54', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '181aa06b-b5cc-4514-a85e-0271c4f49191' User entered 'None (0)'	System	11 Aug 2020 01:32:18
	System	11 Aug 2020 01:32:18

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-10T21:31:56', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '181aa06b-b5cc-4514-a85e-0271c4f49191' User entered 'None (0)'	System	11 Aug 2020 01:32:18
	System	11 Aug 2020 01:32:18

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-10T21:31:58', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '181aa06b-b5cc-4514-a85e-0271c4f49191' User entered 'None (0)'	System	11 Aug 2020 01:32:18
	System	11 Aug 2020 01:32:18

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-10T21:32:03', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '181aa06b-b5cc-4514-a85e-0271c4f49191' User entered 'None (0)'	System	11 Aug 2020 01:32:18
	System	11 Aug 2020 01:32:18

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-10T21:32:05', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '181aa06b-b5cc-4514-a85e-0271c4f49191' User entered 'None (0)'	System	11 Aug 2020 01:32:18
	System	11 Aug 2020 01:32:18

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-10T21:32:07', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '181aa06b-b5cc-4514-a85e-0271c4f49191' User entered 'None (0)'	System	11 Aug 2020 01:32:18
	System	11 Aug 2020 01:32:18

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-10T21:32:12', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '181aa06b-b5cc-4514-a85e-0271c4f49191' User entered 'No (N)'	System	11 Aug 2020 01:32:18
	System	11 Aug 2020 01:32:18

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-08-10T21:32:16', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '181aa06b-b5cc-4514-a85e-0271c4f49191' User entered '10 Aug 2020 21:32'	System	11 Aug 2020 01:32:18
	System	11 Aug 2020 01:32:18

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 19:18:39

US3402225

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 19:18:39

US3402225

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	11 Aug 2020 18:47:00

US3402225

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '11 Aug 2020'	(b) (4) Traci Hull (b) (4)	11 Aug 2020 18:47:00

US3402225

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	11 Aug 2020 18:47:00

US3402225

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Traci Hull (b) (4)	11 Aug 2020 18:47:00

US3402225

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	11 Aug 2020 18:47:05

US3402225

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered '1'	System	11 Aug 2020 18:47:05

US3402225

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	19 Aug 2020 12:29:45

US3402225

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '18 Aug 2020'	(b) (4) Traci Hull (b) (4)	19 Aug 2020 12:29:45

US3402225

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	19 Aug 2020 12:29:45

US3402225

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Traci Hull (b) (4)	19 Aug 2020 12:29:45

US3402225

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	19 Aug 2020 12:29:52

US3402225

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered 'I'	System	19 Aug 2020 12:29:52

US3402225

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	26 Aug 2020 13:22:10

US3402225

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '25 Aug 2020'	(b) (4) Traci Hull (b) (4)	26 Aug 2020 13:22:10

US3402225

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	26 Aug 2020 13:22:10

US3402225

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Traci Hull (b) (4)	26 Aug 2020 13:22:10

US3402225

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	26 Aug 2020 13:22:14

US3402225

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:48:35
User entered '1'	System	26 Aug 2020 13:22:14

US3402225

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:39:17

US3402225

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '1 Sep 2020'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:39:17

US3402225

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Clinic (Clinic)'	(b) (4) Traci Hull (b) (4) (b) (4)	01 Sep 2020 17:39:17

US3402225

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered 'VISIT2'	System	01 Sep 2020 17:39:17

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '1 Sep 2020'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '11:37'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered '1 Sep 2020 11:37'	System	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '36.7' C	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '81'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered 'bpm'	System	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '14'	(b) (4) Traci Hull (b) (4) (b) (4)	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered 'breaths/min'	System	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '114'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered 'mmHg'	System	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '76'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered 'mmHg'	System	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '1 Sep 2020'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '13:25'	(b) (4) Traci Hull (b) (4) (b) (4)	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered '1 Sep 2020 13:25'	System	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '36.9' C	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '72'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered 'bpm'	System	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '14'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered 'breaths/min'	System	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '116'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered 'mmHg'	System	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '82'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered 'mmHg'	System	01 Sep 2020 17:42:34

US3402225

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:42:42

US3402225

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '1 Sep 2020'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:42:42

US3402225

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User closed query 'Per CDM: Childbearing potential noted as "YES" yet pregnancy test not performed. Kindly review and update else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 15:00:52
Query 'Per CDM: Childbearing potential noted as "YES" yet pregnancy test not performed. Kindly review and update else clarify.' answered with 'Data updated' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	17 Sep 2020 19:56:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	17 Sep 2020 19:55:57
User opened query 'Per CDM: Childbearing potential noted as "YES" yet pregnancy test not performed. Kindly review and update else clarify.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 19:48:33
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	01 Sep 2020 17:43:32

US3402225

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '1 Sep 2020' reason for change: Data Entry Error	(b) (4)	17 Sep 2020 19:55:57
User entered empty.	Tammy Kohn (b) (4)	17 Sep 2020 19:55:57
	(b) (4)	
	Traci Hull (b) (4)	01 Sep 2020 17:43:32
	(b) (4)	

US3402225

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Urine (URINE)' reason for change: Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Sep 2020 19:55:57
User entered empty.	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:43:32
	(b) (4)	

US3402225

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error	(b) (4) Tammy Kohn (b) (4)	17 Sep 2020 19:55:57
User entered empty.	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:43:32
	(b) (4)	

US3402225

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User closed query 'Per CDM, please provide response to current question, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:27:58
Query 'Per CDM, please provide response to current question, otherwise clarify.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	12 Oct 2020 11:26:10
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	12 Oct 2020 11:26:04
User opened query 'Per CDM, please provide response to current question, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 07:50:11
User entered empty.	Traci Hull (b) (4) (b) (4)	01 Sep 2020 17:43:32

US3402225

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:43:32

US3402225

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:43:32

US3402225

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered empty.	System	01 Sep 2020 17:43:32

US3402225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Abigail Wine (b) (4)	01 Sep 2020 17:02:06

US3402225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Abigail Wine (b) (4)	01 Sep 2020 17:02:06

US3402225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Abigail Wine (b) (4)	01 Sep 2020 17:02:06

US3402225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 17:02:06

US3402225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '1 Sep 2020'	(b) (4) Abigail Wine (b) (4)	01 Sep 2020 17:02:06

US3402225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '12:44'	(b) (4) Abigail Wine (b) (4)	01 Sep 2020 17:02:06

US3402225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered '1 Sep 2020 12:44'	System	01 Sep 2020 17:02:06

US3402225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Left Arm (LEFT ARM)'	(b) (4) Abigail Wine (b) (4)	01 Sep 2020 17:02:06

US3402225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered 'ONCE'	System	01 Sep 2020 17:02:06

US3402225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 17:02:06

US3402225

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:43:46

US3402225

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '1 Sep 2020'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:43:46

US3402225

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '12:25'	(b) (4) Traci Hull (b) (4) (b) (4)	01 Sep 2020 17:43:46

US3402225

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered '1 Sep 2020 12:25'	System	01 Sep 2020 17:43:46

US3402225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:23:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '1 Sep 2020'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:43:58

US3402225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:23:40

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	01 Sep 2020 17:43:58

US3402225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:23:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:43:58

US3402225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:23:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '12:27'	(b) (4) Traci Hull (b) (4) (b) (4)	01 Sep 2020 17:43:58

US3402225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:23:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered '1 Sep 2020 12:27'	System	01 Sep 2020 17:43:58

US3402225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:23:40

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	01 Sep 2020 17:43:58

US3402225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:23:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:43:58

US3402225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:23:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:43:58

US3402225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:23:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered empty.	System	01 Sep 2020 17:43:58

US3402225

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 17:44:03

US3402225

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered '1'	System	01 Sep 2020 17:44:03

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	01 Sep 2020 17:02:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T13:20:21', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'a594c7a1-8b4b-4b11-a417-6ce239a841d6'	System	01 Sep 2020 17:20:38
User entered 'Yes (Y)'	System	01 Sep 2020 17:20:38

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T13:20:27', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'a594c7a1-8b4b-4b11-a417-6ce239a841d6' User entered '98.4'	System	01 Sep 2020 17:20:38
	System	01 Sep 2020 17:20:38

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T13:20:31', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'a594c7a1-8b4b-4b11-a417-6ce239a841d6'	System	01 Sep 2020 17:20:38
User entered 'No (N)'	System	01 Sep 2020 17:20:38

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T13:20:35', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'a594c7a1-8b4b-4b11-a417-6ce239a841d6' User entered '01 Sep 2020 13:20'	System	01 Sep 2020 17:20:38
	System	01 Sep 2020 17:20:38

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '01 Sep 2020 13:04'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '01 Sep 2020 15:34'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	01 Sep 2020 17:02:06
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T19:51:11', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '7377a55c-19fc-4b14-b3ff-cc5f2f0786bf' User entered 'Yes (Y)'	System	01 Sep 2020 23:55:10
	System	01 Sep 2020 23:55:10

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T19:54:51', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '7377a55c-19fc-4b14-b3ff-cc5f2f0786bf' User entered '97.2'	System	01 Sep 2020 23:55:10
	System	01 Sep 2020 23:55:10

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T19:55:01', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '7377a55c-19fc-4b14-b3ff-cc5f2f0786bf'	System	01 Sep 2020 23:55:10
User entered 'No (N)'	System	01 Sep 2020 23:55:10

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T19:55:08', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '7377a55c-19fc-4b14-b3ff-cc5f2f0786bf'	System	01 Sep 2020 23:55:10
User entered '01 Sep 2020 19:55'	System	01 Sep 2020 23:55:10

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '01 Sep 2020 16:29'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	01 Sep 2020 17:02:06
User entered 'Day 2'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-02T21:48:12', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'e9f91999-2e2e-41f1-85a7-a6e59c7c7266'	System	03 Sep 2020 01:48:29
User entered 'Yes (Y)'	System	03 Sep 2020 01:48:29

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-02T21:48:18', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'e9f91999-2e2e-41f1-85a7-a6e59c7c7266'	System	03 Sep 2020 01:48:29
User entered '97.6'	System	03 Sep 2020 01:48:29

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-02T21:48:23', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'e9f91999-2e2e-41f1-85a7-a6e59c7c7266'	System	03 Sep 2020 01:48:29
User entered 'No (N)'	System	03 Sep 2020 01:48:29

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-02T21:48:28', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'e9f91999-2e2e-41f1-85a7-a6e59c7c7266'	System	03 Sep 2020 01:48:29
User entered '02 Sep 2020 21:48'	System	03 Sep 2020 01:48:29

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	01 Sep 2020 17:02:06
User entered 'Day 3'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-03T20:39:19', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '0b238798-1a36-4f67-9bd9-d2b4a10b51ef' User entered 'Yes (Y)'	System	04 Sep 2020 00:39:40
	System	04 Sep 2020 00:39:40

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-03T20:39:29', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '0b238798-1a36-4f67-9bd9-d2b4a10b51ef' User entered '98.1'	System	04 Sep 2020 00:39:40
	System	04 Sep 2020 00:39:40

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-03T20:39:34', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '0b238798-1a36-4f67-9bd9-d2b4a10b51ef'	System	04 Sep 2020 00:39:40
User entered 'No (N)'	System	04 Sep 2020 00:39:40

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-03T20:39:37', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '0b238798-1a36-4f67-9bd9-d2b4a10b51ef' User entered '03 Sep 2020 20:39'	System	04 Sep 2020 00:39:40
	System	04 Sep 2020 00:39:40

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	01 Sep 2020 17:02:06
User entered 'Day 4'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-04T20:37:05', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'eb0a9262-914e-4950-9679-6cdcdd0ae1df' User entered 'Yes (Y)'	System	05 Sep 2020 00:37:25
	System	05 Sep 2020 00:37:25

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-04T20:37:10', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'eb0a9262-914e-4950-9679-6cdcdd0ae1df' User entered '97.4'	System	05 Sep 2020 00:37:25
	System	05 Sep 2020 00:37:25

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-04T20:37:15', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'eb0a9262-914e-4950-9679-6cdcdd0ae1df'	System	05 Sep 2020 00:37:25
User entered 'No (N)'	System	05 Sep 2020 00:37:25

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-04T20:37:22', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'eb0a9262-914e-4950-9679-6cdcdd0ae1df' User entered '04 Sep 2020 20:37'	System	05 Sep 2020 00:37:25
	System	05 Sep 2020 00:37:25

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	01 Sep 2020 17:02:06
User entered 'Day 5'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T09:37:15', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '0b021f65-f3b1-4e4a-8dc0-2287771c9e20' User entered 'Yes (Y)'	System	06 Sep 2020 13:37:29
	System	06 Sep 2020 13:37:29

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T09:37:20', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '0b021f65-f3b1-4e4a-8dc0-2287771c9e20' User entered '97.0'	System	06 Sep 2020 13:37:29
	System	06 Sep 2020 13:37:29

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T09:37:25', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '0b021f65-f3b1-4e4a-8dc0-2287771c9e20' User entered 'No (N)'	System	06 Sep 2020 13:37:29
	System	06 Sep 2020 13:37:29

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T09:37:28', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '0b021f65-f3b1-4e4a-8dc0-2287771c9e20' User entered '06 Sep 2020 09:37'	System	06 Sep 2020 13:37:29
	System	06 Sep 2020 13:37:29

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	01 Sep 2020 17:02:06
User entered 'Day 6'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T20:52:43', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'cf9bb44b-dc58-4c83-b616-8ae2197f3af1' User entered 'Yes (Y)'	System	07 Sep 2020 00:53:21
	System	07 Sep 2020 00:53:21

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T20:52:49', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'cf9bb44b-dc58-4c83-b616-8ae2197f3af1' User entered '97.2'	System	07 Sep 2020 00:53:21
	System	07 Sep 2020 00:53:21

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T20:52:56', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'cf9bb44b-dc58-4c83-b616-8ae2197f3af1'	System	07 Sep 2020 00:53:21
User entered 'No (N)'	System	07 Sep 2020 00:53:21

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T20:53:17', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'cf9bb44b-dc58-4c83-b616-8ae2197f3af1' User entered '06 Sep 2020 20:53'	System	07 Sep 2020 00:53:21
	System	07 Sep 2020 00:53:21

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	01 Sep 2020 17:02:06
User entered 'Day 7'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-07T19:51:33', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '43c07932-1b47-4303-ac3c-ed28013d2778'	System	07 Sep 2020 23:51:47
User entered 'Yes (Y)'	System	07 Sep 2020 23:51:47

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-07T19:51:38', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '43c07932-1b47-4303-ac3c-ed28013d2778' User entered '97.1'	System	07 Sep 2020 23:51:47
	System	07 Sep 2020 23:51:47

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-07T19:51:41', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '43c07932-1b47-4303-ac3c-ed28013d2778'	System	07 Sep 2020 23:51:47
User entered 'No (N)'	System	07 Sep 2020 23:51:47

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-07T19:51:45', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '43c07932-1b47-4303-ac3c-ed28013d2778' User entered '07 Sep 2020 19:51'	System	07 Sep 2020 23:51:47
	System	07 Sep 2020 23:51:47

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	01 Sep 2020 17:02:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T13:20:44', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '9ce35c41-ca9b-40e7-a549-f9448df07b45'	System	01 Sep 2020 17:21:03
User entered 'Does not interfere with activity (2)'	System	01 Sep 2020 17:21:03

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T13:20:46', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '9ce35c41-ca9b-40e7-a549-f9448df07b45' User entered 'No (N)'	System	01 Sep 2020 17:21:03
	System	01 Sep 2020 17:21:03

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T13:20:50', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '9ce35c41-ca9b-40e7-a549-f9448df07b45'	System	01 Sep 2020 17:21:03
User entered 'No (N)'	System	01 Sep 2020 17:21:03

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T13:20:52', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '9ce35c41-ca9b-40e7-a549-f9448df07b45'	System	01 Sep 2020 17:21:03
User entered 'None (1)'	System	01 Sep 2020 17:21:03

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T13:20:59', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '9ce35c41-ca9b-40e7-a549-f9448df07b45'	System	01 Sep 2020 17:21:03
User entered '01 Sep 2020 13:20'	System	01 Sep 2020 17:21:03

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '01 Sep 2020 13:04'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '01 Sep 2020 15:34'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	01 Sep 2020 17:02:06
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T19:55:13', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '79fbcdef-bbf9-4c67-890b-d6db3302a37b'	System	01 Sep 2020 23:55:28
User entered 'None (1)'	System	01 Sep 2020 23:55:28

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T19:55:16', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '79fbcdef-bbf9-4c67-890b-d6db3302a37b'	System	01 Sep 2020 23:55:28
User entered 'No (N)'	System	01 Sep 2020 23:55:28

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T19:55:18', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '79fbcdef-bbf9-4c67-890b-d6db3302a37b'	System	01 Sep 2020 23:55:28
User entered 'No (N)'	System	01 Sep 2020 23:55:28

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T19:55:21', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '79fbcdef-bbf9-4c67-890b-d6db3302a37b'	System	01 Sep 2020 23:55:28
User entered 'None (1)'	System	01 Sep 2020 23:55:28

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T19:55:27', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '79fbcdef-bbf9-4c67-890b-d6db3302a37b' User entered '01 Sep 2020 19:55'	System	01 Sep 2020 23:55:28
	System	01 Sep 2020 23:55:28

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '01 Sep 2020 16:29'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	01 Sep 2020 17:02:06
User entered 'Day 2'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:40

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-02T21:48:40', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '28ff5a69-3463-4df6-9d58-5434bff23651'	System	03 Sep 2020 01:49:21
User entered 'None (1)'	System	03 Sep 2020 01:49:21

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:40

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-02T21:48:58', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '28ff5a69-3463-4df6-9d58-5434bff23651'	System	03 Sep 2020 01:49:21
User entered 'No (N)'	System	03 Sep 2020 01:49:21

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-02T21:49:01', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '28ff5a69-3463-4df6-9d58-5434bff23651'	System	03 Sep 2020 01:49:21
User entered 'No (N)'	System	03 Sep 2020 01:49:21

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:40

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-02T21:49:11', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '28ff5a69-3463-4df6-9d58-5434bff23651'	System	03 Sep 2020 01:49:21
User entered 'None (1)'	System	03 Sep 2020 01:49:21

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-02T21:49:18', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '28ff5a69-3463-4df6-9d58-5434bff23651' User entered '02 Sep 2020 21:49'	System	03 Sep 2020 01:49:21
	System	03 Sep 2020 01:49:21

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	01 Sep 2020 17:02:06
User entered 'Day 3'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:40

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-03T20:40:26', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '0a921dec-15e7-413e-a83b-aa8edad30322'	System	04 Sep 2020 00:40:44
User entered 'None (1)'	System	04 Sep 2020 00:40:44

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:40

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-03T20:40:30', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '0a921dec-15e7-413e-a83b-aa8edad30322'	System	04 Sep 2020 00:40:44
User entered 'No (N)'	System	04 Sep 2020 00:40:44

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-03T20:40:32', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '0a921dec-15e7-413e-a83b-aa8edad30322'	System	04 Sep 2020 00:40:44
User entered 'No (N)'	System	04 Sep 2020 00:40:44

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:40

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-03T20:40:35', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '0a921dec-15e7-413e-a83b-aa8edad30322'	System	04 Sep 2020 00:40:44
User entered 'None (1)'	System	04 Sep 2020 00:40:44

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-03T20:40:41', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '0a921dec-15e7-413e-a83b-aa8edad30322' User entered '03 Sep 2020 20:40'	System	04 Sep 2020 00:40:44
	System	04 Sep 2020 00:40:44

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	01 Sep 2020 17:02:06
User entered 'Day 4'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:40

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-04T20:37:28', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '4255c30c-0611-4141-8783-b05dfa665695'	System	05 Sep 2020 00:37:48
User entered 'None (1)'	System	05 Sep 2020 00:37:48

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:40

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-04T20:37:31', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '4255c30c-0611-4141-8783-b05dfa665695'	System	05 Sep 2020 00:37:48
User entered 'No (N)'	System	05 Sep 2020 00:37:48

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-04T20:37:34', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '4255c30c-0611-4141-8783-b05dfa665695' User entered 'No (N)'	System	05 Sep 2020 00:37:48
	System	05 Sep 2020 00:37:48

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:40

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-04T20:37:36', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '4255c30c-0611-4141-8783-b05dfa665695'	System	05 Sep 2020 00:37:48
User entered 'None (1)'	System	05 Sep 2020 00:37:48

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-04T20:37:45', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '4255c30c-0611-4141-8783-b05dfa665695' User entered '04 Sep 2020 20:37'	System	05 Sep 2020 00:37:48
	System	05 Sep 2020 00:37:48

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	01 Sep 2020 17:02:06
User entered 'Day 5'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:40

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T09:37:33', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '70afcd51-bae6-4d82-87d2-17325283ada2'	System	06 Sep 2020 13:37:45
User entered 'None (1)'	System	06 Sep 2020 13:37:45

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:40

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T09:37:35', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '70afcd51-bae6-4d82-87d2-17325283ada2' User entered 'No (N)'	System	06 Sep 2020 13:37:45
	System	06 Sep 2020 13:37:45

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T09:37:37', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '70afcd51-bae6-4d82-87d2-17325283ada2'	System	06 Sep 2020 13:37:45
User entered 'No (N)'	System	06 Sep 2020 13:37:45

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:40

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T09:37:40', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '70afcd51-bae6-4d82-87d2-17325283ada2'	System	06 Sep 2020 13:37:45
User entered 'None (1)'	System	06 Sep 2020 13:37:45

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T09:37:42', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '70afcd51-bae6-4d82-87d2-17325283ada2' User entered '06 Sep 2020 09:37'	System	06 Sep 2020 13:37:45
	System	06 Sep 2020 13:37:45

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	01 Sep 2020 17:02:06
User entered 'Day 6'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:40

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T20:54:58', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '572a6ea2-1a26-413f-a8bc-027dfd7fcea1' User entered 'None (1)'	System	07 Sep 2020 00:55:43
	System	07 Sep 2020 00:55:43

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:40

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T20:55:01', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '572a6ea2-1a26-413f-a8bc-027dfd7fcea1'	System	07 Sep 2020 00:55:43
User entered 'No (N)'	System	07 Sep 2020 00:55:43

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T20:55:03', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '572a6ea2-1a26-413f-a8bc-027dfd7fcea1'	System	07 Sep 2020 00:55:43
User entered 'No (N)'	System	07 Sep 2020 00:55:43

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:40

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T20:55:38', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '572a6ea2-1a26-413f-a8bc-027dfd7fcea1'	System	07 Sep 2020 00:55:43
User entered 'None (1)'	System	07 Sep 2020 00:55:43

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T20:55:41', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '572a6ea2-1a26-413f-a8bc-027dfd7fcea1' User entered '06 Sep 2020 20:55'	System	07 Sep 2020 00:55:43
	System	07 Sep 2020 00:55:43

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	01 Sep 2020 17:02:06
User entered 'Day 7'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:40

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-07T19:51:49', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'f965f86f-565c-46ba-9ed3-935fbb9e0cfa'	System	07 Sep 2020 23:52:05
User entered 'None (1)'	System	07 Sep 2020 23:52:05

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:40

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-07T19:51:53', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'f965f86f-565c-46ba-9ed3-935fbb9e0cfa'	System	07 Sep 2020 23:52:05
User entered 'No (N)'	System	07 Sep 2020 23:52:05

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-07T19:51:55', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'f965f86f-565c-46ba-9ed3-935fbb9e0cfa'	System	07 Sep 2020 23:52:05
User entered 'No (N)'	System	07 Sep 2020 23:52:05

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:40

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-07T19:51:57', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'f965f86f-565c-46ba-9ed3-935fbb9e0cfa'	System	07 Sep 2020 23:52:05
User entered 'None (1)'	System	07 Sep 2020 23:52:05

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-07T19:52:02', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'f965f86f-565c-46ba-9ed3-935fbb9e0cfa'	System	07 Sep 2020 23:52:05
User entered '07 Sep 2020 19:52'	System	07 Sep 2020 23:52:05

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	01 Sep 2020 17:02:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T13:21:04', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '95c2d364-cc47-4b18-b2f1-f840942d86b0' User entered 'None (0)'	System	01 Sep 2020 17:21:25
	System	01 Sep 2020 17:21:25

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T13:21:08', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '95c2d364-cc47-4b18-b2f1-f840942d86b0' User entered 'None (0)'	System	01 Sep 2020 17:21:25
	System	01 Sep 2020 17:21:25

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T13:21:10', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '95c2d364-cc47-4b18-b2f1-f840942d86b0' User entered 'None (0)'	System	01 Sep 2020 17:21:25
	System	01 Sep 2020 17:21:25

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T13:21:12', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '95c2d364-cc47-4b18-b2f1-f840942d86b0' User entered 'None (0)'	System	01 Sep 2020 17:21:25
	System	01 Sep 2020 17:21:25

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T13:21:14', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '95c2d364-cc47-4b18-b2f1-f840942d86b0' User entered 'None (0)'	System	01 Sep 2020 17:21:25
	System	01 Sep 2020 17:21:25

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T13:21:15', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '95c2d364-cc47-4b18-b2f1-f840942d86b0' User entered 'None (0)'	System	01 Sep 2020 17:21:25
	System	01 Sep 2020 17:21:25

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T13:21:20', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '95c2d364-cc47-4b18-b2f1-f840942d86b0' User entered 'No (N)'	System	01 Sep 2020 17:21:25
	System	01 Sep 2020 17:21:25

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T13:21:23', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '95c2d364-cc47-4b18-b2f1-f840942d86b0' User entered '01 Sep 2020 13:21'	System	01 Sep 2020 17:21:25
	System	01 Sep 2020 17:21:25

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '01 Sep 2020 13:04'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '01 Sep 2020 15:34'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	01 Sep 2020 17:02:06
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T19:55:32', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'b609c991-3f1b-4d0e-8a96-d3e52321e9dd'	System	01 Sep 2020 23:55:51
User entered 'None (0)'	System	01 Sep 2020 23:55:51

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T19:55:34', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'b609c991-3f1b-4d0e-8a96-d3e52321e9dd' User entered 'None (0)'	System	01 Sep 2020 23:55:51
	System	01 Sep 2020 23:55:51

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T19:55:35', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'b609c991-3f1b-4d0e-8a96-d3e52321e9dd' User entered 'None (0)'	System	01 Sep 2020 23:55:51
	System	01 Sep 2020 23:55:51

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T19:55:38', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'b609c991-3f1b-4d0e-8a96-d3e52321e9dd' User entered 'None (0)'	System	01 Sep 2020 23:55:51
	System	01 Sep 2020 23:55:51

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T19:55:39', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'b609c991-3f1b-4d0e-8a96-d3e52321e9dd' User entered 'None (0)'	System	01 Sep 2020 23:55:51
	System	01 Sep 2020 23:55:51

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T19:55:42', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'b609c991-3f1b-4d0e-8a96-d3e52321e9dd' User entered 'None (0)'	System	01 Sep 2020 23:55:51
	System	01 Sep 2020 23:55:51

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T19:55:46', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'b609c991-3f1b-4d0e-8a96-d3e52321e9dd' User entered 'No (N)'	System	01 Sep 2020 23:55:51
	System	01 Sep 2020 23:55:51

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-01T19:55:49', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'b609c991-3f1b-4d0e-8a96-d3e52321e9dd' User entered '01 Sep 2020 19:55'	System	01 Sep 2020 23:55:51
	System	01 Sep 2020 23:55:51

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '01 Sep 2020 16:29'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	01 Sep 2020 17:02:06
User entered 'Day 2'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-02T21:49:24', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'b173efb3-ac6c-402e-b980-aefda1aa6cbc' User entered 'None (0)'	System	03 Sep 2020 01:49:55
	System	03 Sep 2020 01:49:55

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-02T21:49:26', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'b173efb3-ac6c-402e-b980-aefda1aa6cbc' User entered 'None (0)'	System	03 Sep 2020 01:49:55
	System	03 Sep 2020 01:49:55

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-02T21:49:32', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'b173efb3-ac6c-402e-b980-aefda1aa6cbc' User entered 'None (0)'	System	03 Sep 2020 01:49:55
	System	03 Sep 2020 01:49:55

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-02T21:49:34', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'b173efb3-ac6c-402e-b980-aefda1aa6cbc' User entered 'None (0)'	System	03 Sep 2020 01:49:55
	System	03 Sep 2020 01:49:55

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-02T21:49:37', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'b173efb3-ac6c-402e-b980-aefda1aa6cbc' User entered 'None (0)'	System	03 Sep 2020 01:49:55
	System	03 Sep 2020 01:49:55

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-02T21:49:39', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'b173efb3-ac6c-402e-b980-aefda1aa6cbc' User entered 'None (0)'	System	03 Sep 2020 01:49:55
	System	03 Sep 2020 01:49:55

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:40

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-02T21:49:47', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'b173efb3-ac6c-402e-b980-aefda1aa6cbc' User entered 'No (N)'	System	03 Sep 2020 01:49:55
	System	03 Sep 2020 01:49:55

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-02T21:49:50', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'b173efb3-ac6c-402e-b980-aefda1aa6cbc' User entered '02 Sep 2020 21:49'	System	03 Sep 2020 01:49:55
	System	03 Sep 2020 01:49:55

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	01 Sep 2020 17:02:06
User entered 'Day 3'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-03T20:40:45', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '8bab6fae-b1ef-4112-8c19-5e6df33de626' User entered 'None (0)'	System	04 Sep 2020 00:41:04
	System	04 Sep 2020 00:41:04

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-03T20:40:47', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '8bab6fae-b1ef-4112-8c19-5e6df33de626' User entered 'None (0)'	System	04 Sep 2020 00:41:04
	System	04 Sep 2020 00:41:04

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-03T20:40:50', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '8bab6fae-b1ef-4112-8c19-5e6df33de626' User entered 'None (0)'	System	04 Sep 2020 00:41:04
	System	04 Sep 2020 00:41:04

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-03T20:40:52', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '8bab6fae-b1ef-4112-8c19-5e6df33de626' User entered 'None (0)'	System	04 Sep 2020 00:41:04
	System	04 Sep 2020 00:41:04

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-03T20:40:55', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '8bab6fae-b1ef-4112-8c19-5e6df33de626' User entered 'None (0)'	System	04 Sep 2020 00:41:04
	System	04 Sep 2020 00:41:04

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-03T20:40:57', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '8bab6fae-b1ef-4112-8c19-5e6df33de626' User entered 'None (0)'	System	04 Sep 2020 00:41:04
	System	04 Sep 2020 00:41:04

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:40

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-03T20:40:59', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '8bab6fae-b1ef-4112-8c19-5e6df33de626' User entered 'No (N)'	System	04 Sep 2020 00:41:04
	System	04 Sep 2020 00:41:04

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-03T20:41:02', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '8bab6fae-b1ef-4112-8c19-5e6df33de626' User entered '03 Sep 2020 20:41'	System	04 Sep 2020 00:41:04
	System	04 Sep 2020 00:41:04

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	01 Sep 2020 17:02:06
User entered 'Day 4'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-04T20:37:52', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'f344bb0a-a536-42b7-978c-105949ecee74' User entered 'None (0)'	System	05 Sep 2020 00:38:11
	System	05 Sep 2020 00:38:11

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-04T20:37:54', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'f344bb0a-a536-42b7-978c-105949ecee74' User entered 'None (0)'	System	05 Sep 2020 00:38:11
	System	05 Sep 2020 00:38:11

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-04T20:37:56', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'f344bb0a-a536-42b7-978c-105949ecee74' User entered 'None (0)'	System	05 Sep 2020 00:38:11
	System	05 Sep 2020 00:38:11

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-04T20:37:58', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'f344bb0a-a536-42b7-978c-105949ecee74' User entered 'None (0)'	System	05 Sep 2020 00:38:11
	System	05 Sep 2020 00:38:11

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-04T20:38:01', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'f344bb0a-a536-42b7-978c-105949ecee74' User entered 'None (0)'	System	05 Sep 2020 00:38:11
	System	05 Sep 2020 00:38:11

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-04T20:38:03', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'f344bb0a-a536-42b7-978c-105949ecee74' User entered 'None (0)'	System	05 Sep 2020 00:38:11
	System	05 Sep 2020 00:38:11

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:40

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-04T20:38:05', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'f344bb0a-a536-42b7-978c-105949ecee74' User entered 'No (N)'	System	05 Sep 2020 00:38:11
	System	05 Sep 2020 00:38:11

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-04T20:38:09', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'f344bb0a-a536-42b7-978c-105949ecee74' User entered '04 Sep 2020 20:38'	System	05 Sep 2020 00:38:11
	System	05 Sep 2020 00:38:11

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	01 Sep 2020 17:02:06
User entered 'Day 5'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T09:37:46', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '7b7cdf5d-111c-48d2-9de3-d438ec95b21d' User entered 'None (0)'	System	06 Sep 2020 13:38:03
	System	06 Sep 2020 13:38:03

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T09:37:47', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '7b7cdf5d-111c-48d2-9de3-d438ec95b21d' User entered 'None (0)'	System	06 Sep 2020 13:38:03
	System	06 Sep 2020 13:38:03

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T09:37:49', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '7b7cdf5d-111c-48d2-9de3-d438ec95b21d' User entered 'None (0)'	System	06 Sep 2020 13:38:03
	System	06 Sep 2020 13:38:03

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T09:37:51', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '7b7cdf5d-111c-48d2-9de3-d438ec95b21d' User entered 'None (0)'	System	06 Sep 2020 13:38:03
	System	06 Sep 2020 13:38:03

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T09:37:52', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '7b7cdf5d-111c-48d2-9de3-d438ec95b21d' User entered 'None (0)'	System	06 Sep 2020 13:38:03
	System	06 Sep 2020 13:38:03

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T09:37:54', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '7b7cdf5d-111c-48d2-9de3-d438ec95b21d' User entered 'None (0)'	System	06 Sep 2020 13:38:03
	System	06 Sep 2020 13:38:03

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:40

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T09:37:56', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '7b7cdf5d-111c-48d2-9de3-d438ec95b21d' User entered 'No (N)'	System	06 Sep 2020 13:38:03
	System	06 Sep 2020 13:38:03

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T09:37:59', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '7b7cdf5d-111c-48d2-9de3-d438ec95b21d' User entered '06 Sep 2020 09:37'	System	06 Sep 2020 13:38:03
	System	06 Sep 2020 13:38:03

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	01 Sep 2020 17:02:06
User entered 'Day 6'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T20:55:51', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'a613c1e2-5786-43bf-af88-ce00d6c1431d' User entered 'None (0)'	System	07 Sep 2020 00:56:10
	System	07 Sep 2020 00:56:10

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T20:55:53', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'a613c1e2-5786-43bf-af88-ce00d6c1431d' User entered 'None (0)'	System	07 Sep 2020 00:56:10
	System	07 Sep 2020 00:56:10

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T20:55:55', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'a613c1e2-5786-43bf-af88-ce00d6c1431d' User entered 'None (0)'	System	07 Sep 2020 00:56:10
	System	07 Sep 2020 00:56:10

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T20:55:57', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'a613c1e2-5786-43bf-af88-ce00d6c1431d' User entered 'None (0)'	System	07 Sep 2020 00:56:10
	System	07 Sep 2020 00:56:10

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T20:56:01', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'a613c1e2-5786-43bf-af88-ce00d6c1431d' User entered 'None (0)'	System	07 Sep 2020 00:56:10
	System	07 Sep 2020 00:56:10

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T20:56:03', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'a613c1e2-5786-43bf-af88-ce00d6c1431d' User entered 'None (0)'	System	07 Sep 2020 00:56:10
	System	07 Sep 2020 00:56:10

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:40

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T20:56:05', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'a613c1e2-5786-43bf-af88-ce00d6c1431d' User entered 'No (N)'	System	07 Sep 2020 00:56:10
	System	07 Sep 2020 00:56:10

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-06T20:56:08', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'a613c1e2-5786-43bf-af88-ce00d6c1431d'	System	07 Sep 2020 00:56:10
User entered '06 Sep 2020 20:56'	System	07 Sep 2020 00:56:10

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	01 Sep 2020 17:02:06
User entered 'Day 7'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-07T19:52:06', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '189b3001-14bf-4c17-94df-5364e33b26c2'	System	07 Sep 2020 23:52:23
User entered 'None (0)'	System	07 Sep 2020 23:52:23

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-07T19:52:07', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '189b3001-14bf-4c17-94df-5364e33b26c2'	System	07 Sep 2020 23:52:23
User entered 'None (0)'	System	07 Sep 2020 23:52:23

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-07T19:52:09', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '189b3001-14bf-4c17-94df-5364e33b26c2' User entered 'None (0)'	System	07 Sep 2020 23:52:23
	System	07 Sep 2020 23:52:23

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-07T19:52:11', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '189b3001-14bf-4c17-94df-5364e33b26c2' User entered 'None (0)'	System	07 Sep 2020 23:52:23
	System	07 Sep 2020 23:52:23

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-07T19:52:13', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '189b3001-14bf-4c17-94df-5364e33b26c2' User entered 'None (0)'	System	07 Sep 2020 23:52:23
	System	07 Sep 2020 23:52:23

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-07T19:52:15', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '189b3001-14bf-4c17-94df-5364e33b26c2' User entered 'None (0)'	System	07 Sep 2020 23:52:23
	System	07 Sep 2020 23:52:23

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:40

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-07T19:52:17', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '189b3001-14bf-4c17-94df-5364e33b26c2'	System	07 Sep 2020 23:52:23
User entered 'No (N)'	System	07 Sep 2020 23:52:23

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-09-07T19:52:21', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '189b3001-14bf-4c17-94df-5364e33b26c2' User entered '07 Sep 2020 19:52'	System	07 Sep 2020 23:52:23
	System	07 Sep 2020 23:52:23

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 17:02:06

US3402225

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 17:02:06

US3402225

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	08 Sep 2020 21:02:32

US3402225

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '8 Sep 2020'	(b) (4) Traci Hull (b) (4)	08 Sep 2020 21:02:32

US3402225

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	08 Sep 2020 21:02:32

US3402225

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Traci Hull (b) (4)	08 Sep 2020 21:02:32

US3402225

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	08 Sep 2020 21:02:36

US3402225

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered '1'	System	08 Sep 2020 21:02:36

US3402225

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	16 Sep 2020 12:41:16

US3402225

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '15 Sep 2020'	(b) (4) Traci Hull (b) (4)	16 Sep 2020 12:41:16

US3402225

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	16 Sep 2020 12:41:16

US3402225

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Traci Hull (b) (4)	16 Sep 2020 12:41:16

US3402225

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	16 Sep 2020 12:41:20

US3402225

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered '1'	System	16 Sep 2020 12:41:20

US3402225

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	22 Sep 2020 16:30:31

US3402225

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '22 Sep 2020'	(b) (4) Traci Hull (b) (4)	22 Sep 2020 16:30:31

US3402225

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	22 Sep 2020 16:30:31

US3402225

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Traci Hull (b) (4)	22 Sep 2020 16:30:31

US3402225

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	22 Sep 2020 16:30:35

US3402225

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered 'I'	System	22 Sep 2020 16:30:35

US3402225

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	29 Sep 2020 16:02:11

US3402225

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '29 Sep 2020'	(b) (4) Traci Hull (b) (4)	29 Sep 2020 16:02:11

US3402225

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Clinic (Clinic)'	(b) (4) Traci Hull (b) (4)	29 Sep 2020 16:02:11

US3402225

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered 'VISIT3'	System	29 Sep 2020 16:02:11

US3402225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	29 Sep 2020 16:03:45

US3402225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '29 Sep 2020'	(b) (4) Traci Hull (b) (4)	29 Sep 2020 16:03:45

US3402225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '11:13'	(b) (4) Traci Hull (b) (4) (b) (4)	29 Sep 2020 16:03:45

US3402225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered '29 Sep 2020 11:13'	System	29 Sep 2020 16:03:45

US3402225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '98.1' F	(b) (4) Traci Hull (b) (4)	29 Sep 2020 16:03:45

US3402225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4)	29 Sep 2020 16:03:45

US3402225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered empty.	(b) (4) Traci Hull (b) (4)	29 Sep 2020 16:03:45

US3402225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '83'	(b) (4) Traci Hull (b) (4)	29 Sep 2020 16:03:45

US3402225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered 'bpm'	System	29 Sep 2020 16:03:45

US3402225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '16'	(b) (4) Traci Hull (b) (4)	29 Sep 2020 16:03:45

US3402225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered 'breaths/min'	System	29 Sep 2020 16:03:45

US3402225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '109'	(b) (4) Traci Hull (b) (4) (b) (4)	29 Sep 2020 16:03:45

US3402225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered 'mmHg'	System	29 Sep 2020 16:03:45

US3402225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '73'	(b) (4) Traci Hull (b) (4)	29 Sep 2020 16:03:45

US3402225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered 'mmHg'	System	29 Sep 2020 16:03:45

US3402225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08

US3402225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08

US3402225

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	29 Sep 2020 16:03:52

US3402225

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '29 Sep 2020'	(b) (4) Traci Hull (b) (4)	29 Sep 2020 16:03:52

US3402225

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	29 Sep 2020 16:04:11

US3402225

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '29 Sep 2020'	(b) (4) Traci Hull (b) (4)	29 Sep 2020 16:04:11

US3402225

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered '11:38'	(b) (4) Traci Hull (b) (4) (b) (4)	29 Sep 2020 16:04:11

US3402225

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered '29 Sep 2020 11:38'	System	29 Sep 2020 16:04:11

US3402225

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:16:48
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	29 Sep 2020 16:04:15

US3402225

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered '1'	System	29 Sep 2020 16:04:15

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 64'	System	04 Aug 2020 19:18:39

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-10-04T22:29:32', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '73a7a0f8-c98f-4fec-9224-fc3798c97ecc'	System	05 Oct 2020 02:29:48
User entered 'No (N)'	System	05 Oct 2020 02:29:48

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-10-04T22:29:39', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '73a7a0f8-c98f-4fec-9224-fc3798c97ecc'	System	05 Oct 2020 02:29:48
User entered 'No (N)'	System	05 Oct 2020 02:29:48

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-10-04T22:29:44', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '73a7a0f8-c98f-4fec-9224-fc3798c97ecc' User entered '04 Oct 2020 22:29:44'	System	05 Oct 2020 02:29:48
	System	05 Oct 2020 02:29:48

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered '04 Oct 2020 00:01'	System	04 Aug 2020 19:18:39

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered '08 Oct 2020 23:59'	System	04 Aug 2020 19:18:39

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 71'	System	04 Aug 2020 19:18:39

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-10-12T10:19:56', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'dc5d6830-9964-431d-9374-bed48972ee03'	System	12 Oct 2020 14:20:07
User entered 'No (N)'	System	12 Oct 2020 14:20:07

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-10-12T10:19:59', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'dc5d6830-9964-431d-9374-bed48972ee03'	System	12 Oct 2020 14:20:07
User entered 'No (N)'	System	12 Oct 2020 14:20:07

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-10-12T10:20:03', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'dc5d6830-9964-431d-9374-bed48972ee03' User entered '12 Oct 2020 10:20:03'	System	12 Oct 2020 14:20:07
	System	12 Oct 2020 14:20:07

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered '11 Oct 2020 00:01'	System	04 Aug 2020 19:18:39

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered '15 Oct 2020 23:59'	System	04 Aug 2020 19:18:39

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 78'	System	04 Aug 2020 19:18:39

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-10-18T09:02:01', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '4a66703b-aa1b-450a-8a41-673c61a8015b'	System	18 Oct 2020 13:02:11
User entered 'No (N)'	System	18 Oct 2020 13:02:11

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-10-18T09:02:05', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '4a66703b-aa1b-450a-8a41-673c61a8015b'	System	18 Oct 2020 13:02:11
User entered 'No (N)'	System	18 Oct 2020 13:02:11

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-10-18T09:02:08', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '4a66703b-aa1b-450a-8a41-673c61a8015b' User entered '18 Oct 2020 09:02:08'	System	18 Oct 2020 13:02:11
	System	18 Oct 2020 13:02:11

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered '18 Oct 2020 00:01'	System	04 Aug 2020 19:18:39

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered '22 Oct 2020 23:59'	System	04 Aug 2020 19:18:39

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 92'	System	04 Aug 2020 19:18:39

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-11-01T09:07:04', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '46422e28-f15a-4501-8976-f38cbc64eb25'	System	01 Nov 2020 14:07:16
User entered 'No (N)'	System	01 Nov 2020 14:07:16

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-11-01T09:07:07', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '46422e28-f15a-4501-8976-f38cbc64eb25'	System	01 Nov 2020 14:07:16
User entered 'No (N)'	System	01 Nov 2020 14:07:16

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-11-01T09:07:11', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '46422e28-f15a-4501-8976-f38cbc64eb25' User entered '01 Nov 2020 09:07:11'	System	01 Nov 2020 14:07:16
	System	01 Nov 2020 14:07:16

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered '01 Nov 2020 00:01'	System	04 Aug 2020 19:18:39

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered '05 Nov 2020 23:59'	System	04 Aug 2020 19:18:39

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 99'	System	04 Aug 2020 19:18:39

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-11-08T22:20:13', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'b1c8a859-1937-4ae7-8fe3-7fdbd3f2b5af'	System	09 Nov 2020 03:20:22
User entered 'No (N)'	System	09 Nov 2020 03:20:22

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-11-08T22:20:16', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'b1c8a859-1937-4ae7-8fe3-7fdbd3f2b5af'	System	09 Nov 2020 03:20:22
User entered 'No (N)'	System	09 Nov 2020 03:20:22

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-11-08T22:20:19', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'b1c8a859-1937-4ae7-8fe3-7fdbd3f2b5af' User entered '08 Nov 2020 22:20:19'	System	09 Nov 2020 03:20:22
	System	09 Nov 2020 03:20:22

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered '08 Nov 2020 00:01'	System	04 Aug 2020 19:18:39

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered '12 Nov 2020 23:59'	System	04 Aug 2020 19:18:39

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered 'Day 106'	System	04 Aug 2020 19:18:39

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-11-15T14:23:11', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'e47160bd-4b83-43d1-8c06-e8d0b34b24e8'	System	15 Nov 2020 19:23:20
User entered 'No (N)'	System	15 Nov 2020 19:23:20

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-11-15T14:23:13', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'e47160bd-4b83-43d1-8c06-e8d0b34b24e8'	System	15 Nov 2020 19:23:20
User entered 'No (N)'	System	15 Nov 2020 19:23:20

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-11-15T14:23:16', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'e47160bd-4b83-43d1-8c06-e8d0b34b24e8' User entered '15 Nov 2020 14:23:16'	System	15 Nov 2020 19:23:20
	System	15 Nov 2020 19:23:20

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered '15 Nov 2020 00:01'	System	04 Aug 2020 19:18:39

US3402225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:08:34
Data entry locked.	System	04 Aug 2020 19:18:39
User entered '19 Nov 2020 23:59'	System	04 Aug 2020 19:18:39

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-11-22T13:43:54', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '2defd1cd-523a-4e27-9c2b-572fbcab38dc'	System	22 Nov 2020 18:44:11
User entered 'No (N)'	System	22 Nov 2020 18:44:11

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with 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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-11-22T13:44:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '2defd1cd-523a-4e27-9c2b-572fbcab38dc'	System	22 Nov 2020 18:44:11
User entered 'No (N)'	System	22 Nov 2020 18:44:11

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-11-22T13:44:05', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '2defd1cd-523a-4e27-9c2b-572fbcab38dc' User entered '22 Nov 2020 13:44:05'	System	22 Nov 2020 18:44:11
	System	22 Nov 2020 18:44:11

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-11-28T13:49:01', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '2cba2b58-9732-4751-857e-073224eff1a3'	System	28 Nov 2020 18:49:11
User entered 'No (N)'	System	28 Nov 2020 18:49:11

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with 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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-11-28T13:49:05', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '2cba2b58-9732-4751-857e-073224eff1a3'	System	28 Nov 2020 18:49:11
User entered 'No (N)'	System	28 Nov 2020 18:49:11

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-11-28T13:49:08', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '2cba2b58-9732-4751-857e-073224eff1a3'	System	28 Nov 2020 18:49:11
User entered '28 Nov 2020 13:49:08'	System	28 Nov 2020 18:49:11

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-12-04T13:59:41', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '5e9240b4-35be-499f-a505-f05fe07f3119'	System	04 Dec 2020 18:59:52
User entered 'No (N)'	System	04 Dec 2020 18:59:52

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with 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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-12-04T13:59:45', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '5e9240b4-35be-499f-a505-f05fe07f3119'	System	04 Dec 2020 18:59:52
User entered 'No (N)'	System	04 Dec 2020 18:59:52

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-12-04T13:59:49', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '5e9240b4-35be-499f-a505-f05fe07f3119' User entered '04 Dec 2020 13:59:49'	System	04 Dec 2020 18:59:52
	System	04 Dec 2020 18:59:52

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-12-10T06:59:46', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '2ff8fbe8-076b-4997-b065-b5d8a74547d1'	System	10 Dec 2020 12:00:04
User entered 'No (N)'	System	10 Dec 2020 12:00:04

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with 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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-12-10T06:59:51', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '2ff8fbe8-076b-4997-b065-b5d8a74547d1'	System	10 Dec 2020 12:00:04
User entered 'No (N)'	System	10 Dec 2020 12:00:04

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-12-10T06:59:57', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '2ff8fbe8-076b-4997-b065-b5d8a74547d1' User entered '10 Dec 2020 06:59:57'	System	10 Dec 2020 12:00:04
	System	10 Dec 2020 12:00:04

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-12-17T20:34:23', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '84f59b38-dd4e-428b-a022-f06a35f37a0a'	System	18 Dec 2020 01:34:43
User entered 'No (N)'	System	18 Dec 2020 01:34:43

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with 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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-12-17T20:34:33', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '84f59b38-dd4e-428b-a022-f06a35f37a0a'	System	18 Dec 2020 01:34:43
User entered 'No (N)'	System	18 Dec 2020 01:34:43

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-12-17T20:34:38', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '84f59b38-dd4e-428b-a022-f06a35f37a0a' User entered '17 Dec 2020 20:34:38'	System	18 Dec 2020 01:34:43
	System	18 Dec 2020 01:34:43

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-12-24T07:03:27', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '2ee83f0c-027e-44fd-baea-ff53e0ffa673'	System	24 Dec 2020 12:03:47
User entered 'No (N)'	System	24 Dec 2020 12:03:47

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with 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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-12-24T07:03:40', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '2ee83f0c-027e-44fd-baea-ff53e0ffa673'	System	24 Dec 2020 12:03:47
User entered 'No (N)'	System	24 Dec 2020 12:03:47

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-12-24T07:03:45', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '2ee83f0c-027e-44fd-baea-ff53e0ffa673'	System	24 Dec 2020 12:03:47
User entered '24 Dec 2020 07:03:45'	System	24 Dec 2020 12:03:47

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-12-31T15:19:35', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '05f0456a-6162-48b1-ac9b-6596fa97e7bc' User entered 'No (N)'	System	31 Dec 2020 20:19:56
	System	31 Dec 2020 20:19:56

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with 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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-12-31T15:19:46', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '05f0456a-6162-48b1-ac9b-6596fa97e7bc' User entered 'No (N)'	System	31 Dec 2020 20:19:56
	System	31 Dec 2020 20:19:56

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2020-12-31T15:19:52', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '05f0456a-6162-48b1-ac9b-6596fa97e7bc' User entered '31 Dec 2020 15:19:52'	System	31 Dec 2020 20:19:56
	System	31 Dec 2020 20:19:56

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-01-07T08:44:07', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'eddf4113-52e6-4ad7-82c3-eb9a62d837d1'	System	07 Jan 2021 13:44:15
User entered 'No (N)'	System	07 Jan 2021 13:44:15

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with 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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-01-07T08:44:09', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'eddf4113-52e6-4ad7-82c3-eb9a62d837d1' User entered 'No (N)'	System	07 Jan 2021 13:44:15
	System	07 Jan 2021 13:44:15

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-01-07T08:44:13', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'eddf4113-52e6-4ad7-82c3-eb9a62d837d1' User entered '07 Jan 2021 08:44:13'	System	07 Jan 2021 13:44:15
	System	07 Jan 2021 13:44:15

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-01-14T09:09:56', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '1680a0c2-35dc-44e2-8af2-8dd342e52be9'	System	14 Jan 2021 14:10:09
User entered 'No (N)'	System	14 Jan 2021 14:10:09

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with 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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-01-14T09:10:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '1680a0c2-35dc-44e2-8af2-8dd342e52be9'	System	14 Jan 2021 14:10:09
User entered 'No (N)'	System	14 Jan 2021 14:10:09

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-01-14T09:10:04', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '1680a0c2-35dc-44e2-8af2-8dd342e52be9' User entered '14 Jan 2021 09:10:04'	System	14 Jan 2021 14:10:09
	System	14 Jan 2021 14:10:09

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-01-21T15:25:57', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'b363f1c9-c2fb-475d-9205-de079dc55827'	System	21 Jan 2021 20:26:08
User entered 'No (N)'	System	21 Jan 2021 20:26:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with 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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-01-21T15:26:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'b363f1c9-c2fb-475d-9205-de079dc55827'	System	21 Jan 2021 20:26:08
User entered 'No (N)'	System	21 Jan 2021 20:26:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-01-21T15:26:03', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'b363f1c9-c2fb-475d-9205-de079dc55827'	System	21 Jan 2021 20:26:08
User entered '21 Jan 2021 15:26:03'	System	21 Jan 2021 20:26:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-01-29T16:50:32', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '3ed89dcf-ba10-4d69-80d5-9a52bc41d82f'	System	29 Jan 2021 21:50:45
User entered 'No (N)'	System	29 Jan 2021 21:50:45

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with 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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-01-29T16:50:39', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '3ed89dcf-ba10-4d69-80d5-9a52bc41d82f' User entered 'No (N)'	System	29 Jan 2021 21:50:45
	System	29 Jan 2021 21:50:45

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-01-29T16:50:42', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '3ed89dcf-ba10-4d69-80d5-9a52bc41d82f' User entered '29 Jan 2021 16:50:42'	System	29 Jan 2021 21:50:45
	System	29 Jan 2021 21:50:45

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-02-04T20:43:50', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '425233f3-3407-48b7-b10f-7dd063c220d5'	System	05 Feb 2021 01:47:52
User entered 'Yes (Y)'	System	05 Feb 2021 01:47:52

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with 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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-02-04T20:43:55', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '425233f3-3407-48b7-b10f-7dd063c220d5'	System	05 Feb 2021 01:47:52
User entered 'No (N)'	System	05 Feb 2021 01:47:52

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-02-04T20:43:59', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '425233f3-3407-48b7-b10f-7dd063c220d5'	System	05 Feb 2021 01:47:52
User entered 'No (N)'	System	05 Feb 2021 01:47:52

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-02-04T20:47:40', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '425233f3-3407-48b7-b10f-7dd063c220d5'	System	05 Feb 2021 01:47:52
User entered 'No (N)'	System	05 Feb 2021 01:47:52

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-02-04T20:47:48', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '425233f3-3407-48b7-b10f-7dd063c220d5'	System	05 Feb 2021 01:47:52
User entered '04 Feb 2021 20:47:48'	System	05 Feb 2021 01:47:52

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-02-11T05:39:01', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '7e7f5aa6-bfda-470f-9666-41337123b574'	System	11 Feb 2021 10:39:52
User entered 'Yes (Y)'	System	11 Feb 2021 10:39:52

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with 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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-02-11T05:39:12', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '7e7f5aa6-bfda-470f-9666-41337123b574'	System	11 Feb 2021 10:39:52
User entered 'No (N)'	System	11 Feb 2021 10:39:52

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-02-11T05:39:24', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '7e7f5aa6-bfda-470f-9666-41337123b574'	System	11 Feb 2021 10:39:52
User entered 'No (N)'	System	11 Feb 2021 10:39:52

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-02-11T05:39:31', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '7e7f5aa6-bfda-470f-9666-41337123b574'	System	11 Feb 2021 10:39:52
User entered 'Yes (Y)'	System	11 Feb 2021 10:39:52

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-02-11T05:39:38', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '7e7f5aa6-bfda-470f-9666-41337123b574'	System	11 Feb 2021 10:39:52
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Feb 2021 10:39:52

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-02-11T05:39:42', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '7e7f5aa6-bfda-470f-9666-41337123b574' User entered '11 Feb 2021 05:39:42'	System	11 Feb 2021 10:39:52
	System	11 Feb 2021 10:39:52

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-02-18T16:29:06', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '74773f4b-63f9-419e-b952-13a71a511196'	System	18 Feb 2021 21:29:17
User entered 'No (N)'	System	18 Feb 2021 21:29:17

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with 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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-02-18T16:28:19', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '74773f4b-63f9-419e-b952-13a71a511196'	System	18 Feb 2021 21:29:17
User entered 'No (N)'	System	18 Feb 2021 21:29:17

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-02-18T16:29:12', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '74773f4b-63f9-419e-b952-13a71a511196' User entered '18 Feb 2021 16:29:12'	System	18 Feb 2021 21:29:17
	System	18 Feb 2021 21:29:17

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-02-25T10:04:18-05:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '746539e0-4e8b-431b-8a0c-9acaab6fd67e'	System	25 Feb 2021 15:04:29
User entered 'No (N)'	System	25 Feb 2021 15:04:29

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with 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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-02-25T10:04:21-05:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '746539e0-4e8b-431b-8a0c-9acaab6fd67e'	System	25 Feb 2021 15:04:29
User entered 'No (N)'	System	25 Feb 2021 15:04:29

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-02-25T10:04:24-05:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '746539e0-4e8b-431b-8a0c-9acaab6fd67e' User entered '25 Feb 2021 15:04:24'	System	25 Feb 2021 15:04:29
	System	25 Feb 2021 15:04:29

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-03-06T17:09:21-05:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '23e4ec12-daf4-4764-a1e5-960c29ac5155'	System	06 Mar 2021 22:09:33
User entered 'No (N)'	System	06 Mar 2021 22:09:33

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with 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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-03-06T17:09:24-05:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '23e4ec12-daf4-4764-a1e5-960c29ac5155'	System	06 Mar 2021 22:09:33
User entered 'No (N)'	System	06 Mar 2021 22:09:33

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-03-06T17:09:27-05:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '23e4ec12-daf4-4764-a1e5-960c29ac5155'	System	06 Mar 2021 22:09:33
User entered '06 Mar 2021 17:09:27'	System	06 Mar 2021 22:09:33

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-03-12T10:04:04-05:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'f9401f00-70bf-4dcd-b8f5-ff438270faac'	System	12 Mar 2021 15:04:14
User entered 'No (N)'	System	12 Mar 2021 15:04:14

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with 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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-03-12T10:04:07-05:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'f9401f00-70bf-4dcd-b8f5-ff438270faac'	System	12 Mar 2021 15:04:14
User entered 'No (N)'	System	12 Mar 2021 15:04:14

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-03-12T10:04:10-05:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'f9401f00-70bf-4dcd-b8f5-ff438270faac'	System	12 Mar 2021 15:04:14
User entered '12 Mar 2021 10:04:10'	System	12 Mar 2021 15:04:14

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-03-19T19:33:37-04:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'c415451e-948f-4cef-83d9-f67d9b26a2d9'	System	19 Mar 2021 23:33:49
User entered 'No (N)'	System	19 Mar 2021 23:33:49

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with 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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-03-19T19:33:40-04:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'c415451e-948f-4cef-83d9-f67d9b26a2d9'	System	19 Mar 2021 23:33:49
User entered 'No (N)'	System	19 Mar 2021 23:33:49

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-03-19T19:33:44-04:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'c415451e-948f-4cef-83d9-f67d9b26a2d9'	System	19 Mar 2021 23:33:49
User entered '19 Mar 2021 19:33:44'	System	19 Mar 2021 23:33:49

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-03-25T20:52:41-04:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '0b5f20f1-b838-4590-b703-75a99e7f5174'	System	26 Mar 2021 00:52:52
User entered 'No (N)'	System	26 Mar 2021 00:52:52

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with 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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-03-25T20:52:43-04:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '0b5f20f1-b838-4590-b703-75a99e7f5174'	System	26 Mar 2021 00:52:52
User entered 'No (N)'	System	26 Mar 2021 00:52:52

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-03-25T20:52:46-04:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '0b5f20f1-b838-4590-b703-75a99e7f5174' User entered '25 Mar 2021 20:52:46'	System	26 Mar 2021 00:52:52
	System	26 Mar 2021 00:52:52

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-04-03T12:00:26-04:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'caa7891a-8714-4234-bb3a-db00240ff5f0'	System	03 Apr 2021 16:01:27
User entered 'No (N)'	System	03 Apr 2021 16:01:27

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with 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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-04-03T12:00:29-04:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'caa7891a-8714-4234-bb3a-db00240ff5f0'	System	03 Apr 2021 16:01:27
User entered 'No (N)'	System	03 Apr 2021 16:01:27

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-04-03T12:00:36-04:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'caa7891a-8714-4234-bb3a-db00240ff5f0'	System	03 Apr 2021 16:01:27
User entered '03 Apr 2021 12:00:36'	System	03 Apr 2021 16:01:27

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-04-10T16:41:55-04:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'eae12e14-04f6-457d-92fd-4b0f656cbfc2'	System	10 Apr 2021 20:42:16
User entered 'Yes (Y)'	System	10 Apr 2021 20:42:16

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with 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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-04-10T16:41:58-04:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'eae12e14-04f6-457d-92fd-4b0f656cbfc2'	System	10 Apr 2021 20:42:16
User entered 'No (N)'	System	10 Apr 2021 20:42:16

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-04-10T16:42:01-04:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'eae12e14-04f6-457d-92fd-4b0f656cbfc2'	System	10 Apr 2021 20:42:16
User entered 'No (N)'	System	10 Apr 2021 20:42:16

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-04-10T16:42:08-04:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'eae12e14-04f6-457d-92fd-4b0f656cbfc2'	System	10 Apr 2021 20:42:16
User entered 'No (N)'	System	10 Apr 2021 20:42:16

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-04-10T16:42:12-04:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'eae12e14-04f6-457d-92fd-4b0f656cbfc2'	System	10 Apr 2021 20:42:16
User entered '10 Apr 2021 16:42:12'	System	10 Apr 2021 20:42:16

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-04-16T14:37:16-04:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '8f55c570-6c96-4a9a-8efe-acc9316cddff'	System	16 Apr 2021 18:37:39
User entered 'No (N)'	System	16 Apr 2021 18:37:39

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with 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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-04-16T14:37:19-04:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '8f55c570-6c96-4a9a-8efe-acc9316cddff'	System	16 Apr 2021 18:37:39
User entered 'No (N)'	System	16 Apr 2021 18:37:39

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-04-16T14:37:22-04:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '8f55c570-6c96-4a9a-8efe-acc9316cddff'	System	16 Apr 2021 18:37:39
User entered '16 Apr 2021 14:37:22'	System	16 Apr 2021 18:37:39

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-04-26T19:53:12-04:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'cf8cbb9a-7bde-428c-ba87-24e0b493518d'	System	26 Apr 2021 23:53:59
User entered 'No (N)'	System	26 Apr 2021 23:53:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with 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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-04-26T19:53:20-04:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'cf8cbb9a-7bde-428c-ba87-24e0b493518d'	System	26 Apr 2021 23:53:59
User entered 'Yes (Y)'	System	26 Apr 2021 23:53:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-04-26T19:53:37-04:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'cf8cbb9a-7bde-428c-ba87-24e0b493518d'	System	26 Apr 2021 23:53:59
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Apr 2021 23:53:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-04-26T19:53:49-04:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'cf8cbb9a-7bde-428c-ba87-24e0b493518d'	System	26 Apr 2021 23:53:59
User entered '26 Apr 2021 19:53:49'	System	26 Apr 2021 23:53:59

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-05-02T16:05:09-04:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '16cd1f1c-a696-40d9-8328-ae90b70d427d'	System	02 May 2021 20:05:24
User entered 'No (N)'	System	02 May 2021 20:05:24

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

Have you been exposed to someone with 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 (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-05-02T16:05:14-04:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '16cd1f1c-a696-40d9-8328-ae90b70d427d'	System	02 May 2021 20:05:24
User entered 'No (N)'	System	02 May 2021 20:05:24

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-05-02T16:05:18-04:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: '16cd1f1c-a696-40d9-8328-ae90b70d427d' User entered '02 May 2021 16:05:18'	System	02 May 2021 20:05:24
	System	02 May 2021 20:05:24

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 12:43:08

US3402225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:43:08
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 12:43:08

US3402225

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:23:40

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:29:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-03-02T13:38:53-05:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'a85512ed-2c67-41ce-ab1c-309243aa74ab'	System	02 Mar 2021 18:39:19
User entered 'Yes (Y)'	System	02 Mar 2021 18:39:19

US3402225

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:23:40

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:29:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-03-02T13:39:05-05:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'a85512ed-2c67-41ce-ab1c-309243aa74ab'	System	02 Mar 2021 18:39:19
User entered 'No (N)'	System	02 Mar 2021 18:39:19

US3402225

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:23:40

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:29:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CA39D62-1692-4575-A562-8881059A141F)', Time: '2021-03-02T13:39:09-05:00', User OID: 'PatientReportedOutcome (US3402225)', ODM File OID: 'a85512ed-2c67-41ce-ab1c-309243aa74ab' User entered '02 Mar 2021 13:39:09'	System	02 Mar 2021 18:39:19
	System	02 Mar 2021 18:39:19

US3402225

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:21:19
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	27 Oct 2020 19:32:02
	(b) (4)	

US3402225

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:21:19
User entered '27 Oct 2020'	(b) (4) Tammy Kohn (b) (4)	27 Oct 2020 19:32:02
	(b) (4)	

US3402225

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:21:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Tammy Kohn (b) (4)	27 Oct 2020 19:32:02

US3402225

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:21:19
User entered empty.	(b) (4) Tammy Kohn (b) (4)	27 Oct 2020 19:32:02
	(b) (4)	

US3402225

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:21:19
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	27 Oct 2020 19:32:11

US3402225

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:08
User entered 'I'	System	27 Oct 2020 19:32:11

US3402225

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	30 Nov 2020 19:44:33

US3402225

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '30 Nov 2020'	(b) (4) Traci Hull (b) (4)	30 Nov 2020 19:44:33

US3402225

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	30 Nov 2020 19:44:33

US3402225

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered empty.	(b) (4) Traci Hull (b) (4)	30 Nov 2020 19:44:33

US3402225

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	30 Nov 2020 19:44:24

US3402225

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:05
User entered 'I'	System	30 Nov 2020 19:44:24

US3402225

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	28 Dec 2020 19:47:31

US3402225

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered '28 Dec 2020'	(b) (4) Traci Hull (b) (4)	28 Dec 2020 19:47:31

US3402225

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	28 Dec 2020 19:47:31

US3402225

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered empty.	(b) (4) Traci Hull (b) (4)	28 Dec 2020 19:47:31

US3402225

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	28 Dec 2020 19:47:36

US3402225

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:05
User entered 'I'	System	28 Dec 2020 19:47:36

US3402225

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	26 Jan 2021 21:21:05
	(b) (4)	

US3402225

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered '26 Jan 2021'	(b) (4) Tammy Kohn (b) (4)	26 Jan 2021 21:21:05
	(b) (4)	

US3402225

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Tammy Kohn (b) (4)	26 Jan 2021 21:21:05

US3402225

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered empty.	(b) (4) Tammy Kohn (b) (4)	26 Jan 2021 21:21:05
	(b) (4)	

US3402225

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	26 Jan 2021 21:21:09

US3402225

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:05
User entered '1'	System	26 Jan 2021 21:21:09

US3402225

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User closed query 'Per CDM: Thank you for record the VS form. However, the response for Were vital signs assessed? is No. Visit 4 Day 209 and Visit OL-D29 are both dated 9 Mar 2021. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor with the same response Yes or No. Please review Reconcile and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 08:02:25
Query 'Per CDM: Thank you for record the VS form. However, the response for Were vital signs assessed? is No. Visit 4 Day 209 and Visit OL-D29 are both dated 9 Mar 2021. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor with the same response Yes or No. Please review Reconcile and update as appropriate. ' answered with 'updated' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 20:20:51
User opened query 'Per CDM: Thank you for record the VS form. However, the response for Were vital signs assessed? is No. Visit 4 Day 209 and Visit OL-D29 are both dated 9 Mar 2021. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor with the same response Yes or No. Please review Reconcile and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 16:33:28
User closed query 'Per CDM: Visit 4 Day 209 and Visit OL-D29 are both dated 9 Mar 2021, however, Were vital signs assessed?' is not completed at this visit but at OL-D29 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 16:33:28

US3402225

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Query 'Per CDM: Visit 4 Day 209 and Visit OL-D29 are both dated 9 Mar 2021, however, Were vital signs assessed?' is not completed at this visit but at OL-D29 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor. Please review and update as appropriate. answered with 'updated' (Site from DM).	Traci Hull (b) (4) (b) (4)	30 Mar 2021 19:15:59
User opened query 'Per CDM: Visit 4 Day 209 and Visit OL-D29 are both dated 9 Mar 2021, however, Were vital signs assessed?' is not completed at this visit but at OL-D29 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 16:20:30
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	09 Mar 2021 20:54:27

US3402225

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered '09 Mar 2021'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:54:27

US3402225

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered 'Clinic (Clinic)'	(b) (4) Traci Hull (b) (4) (b) (4)	09 Mar 2021 20:54:27

US3402225

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:05
User entered 'VISIT4'	System	09 Mar 2021 20:54:27

US3402225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:05
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:51:49
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	31 Mar 2021 20:20:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 20:20:58
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	31 Mar 2021 20:20:36
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 19:15:51

US3402225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:05
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:51:49
User entered '09 Mar 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 20:20:36
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 19:15:51

US3402225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered '14:19' reason for change: Data Entry Error	(b) (4)	31 Mar 2021 20:20:36
User entered empty.	Tammy Kohn (b) (4)	30 Mar 2021 19:15:51
	(b) (4)	

US3402225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:05
User entered '09 Mar 2021 14:19'	System	31 Mar 2021 20:20:36
User entered empty.	System	30 Mar 2021 19:15:51

US3402225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered '36.7' C reason for change: Data Entry Error	(b) (4)	31 Mar 2021 20:20:36
User entered empty.	Tammy Kohn (b) (4)	30 Mar 2021 19:15:51
	(b) (4)	

US3402225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:05
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:51:49
User entered 'Oral (Oral)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 20:20:36
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 19:15:51

US3402225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered empty.	(b) (4) Traci Hull (b) (4)	30 Mar 2021 19:15:51

US3402225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered '85' reason for change: Data Entry Error	(b) (4)	31 Mar 2021 20:20:36
User entered empty.	Tammy Kohn (b) (4)	30 Mar 2021 19:15:51
	(b) (4)	

US3402225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:05
User entered 'bpm'	System	31 Mar 2021 20:20:36
User entered empty.	System	30 Mar 2021 19:15:51

US3402225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered '14' reason for change: Data Entry Error	(b) (4)	31 Mar 2021 20:20:36
User entered empty.	Tammy Kohn (b) (4)	30 Mar 2021 19:15:51
	(b) (4)	

US3402225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:05
User entered 'breaths/min'	System	31 Mar 2021 20:20:36
User entered empty.	System	30 Mar 2021 19:15:51

US3402225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered '113' reason for change: Data Entry Error	(b) (4)	31 Mar 2021 20:20:36
User entered empty.	Tammy Kohn (b) (4)	30 Mar 2021 19:15:51
	(b) (4)	

US3402225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:05
User entered 'mmHg'	System	31 Mar 2021 20:20:36
User entered empty.	System	30 Mar 2021 19:15:51

US3402225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered '66' reason for change: Data Entry Error	(b) (4)	31 Mar 2021 20:20:36
User entered empty.	Tammy Kohn (b) (4)	31 Mar 2021 20:20:36
	(b) (4)	
	Traci Hull (b) (4)	30 Mar 2021 19:15:51
	(b) (4)	

US3402225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:05
User entered 'mmHg'	System	31 Mar 2021 20:20:36
User entered empty.	System	30 Mar 2021 19:15:51

US3402225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:05

US3402225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:05

US3402225

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:54:46

US3402225

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered empty.	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:54:46

US3402225

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:55:05

US3402225

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered '09 Mar 2021'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:55:05

US3402225

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered '14:42'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:55:05

US3402225

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:05
User entered '09 Mar 2021 14:42'	System	09 Mar 2021 20:55:05

US3402225

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:05
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:55:11

US3402225

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:05
User entered '1'	System	09 Mar 2021 20:55:11

US3402225

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	31 Mar 2021 14:57:31
	(b) (4)	

US3402225

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
	(b) (4)	
User entered '31 Mar 2021'	Traci Hull (b) (4)	31 Mar 2021 14:57:31
	(b) (4)	

US3402225

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4) (b) (4)	31 Mar 2021 14:57:31

US3402225

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	31 Mar 2021 14:57:31
	(b) (4)	

US3402225

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	31 Mar 2021 14:57:35
	(b) (4)	

US3402225

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Mar 2021 14:57:35

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:24:40

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '18 Jan 2021'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:24:40

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Clinic (Clinic)'	(b) (4) Traci Hull (b) (4) (b) (4)	18 Jan 2021 16:24:40

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered 'UNBLND_DECIDE'	System	18 Jan 2021 16:24:40

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:23:40

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '06 Jan 2021'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:25:26

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:23:40

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '0'	(b) (4) Tammy Kohn (b) (4)	18 Mar 2021 20:06:59
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 11:24:23

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:23:40

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:25:26

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:23:40

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	
Amendment Manager inserted this DataPoint.	Tammy Kohn (b) (4)	18 Mar 2021 20:06:59
	(b) (4)	
	System	06 Mar 2021 11:24:23

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:23:40

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '18 Jan 2021'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:25:26

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:23:40

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Placebo (Placebo)'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:25:26

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:23:40

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 06:14:11
User entered 'Placebo (Placebo)'	Traci Hull (b) (4)	18 Jan 2021 16:25:26
	(b) (4)	

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:23:40

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 06:14:11
User entered 'Placebo (Placebo)'	Traci Hull (b) (4)	18 Jan 2021 16:25:26
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:23:40

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:25:26

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:23:40

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered '1'	System	18 Jan 2021 16:25:26

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:23:40

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered '1'	System	18 Jan 2021 16:25:26

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:40

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:40

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:40

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered empty.	System	18 Jan 2021 16:27:14
DataPoint set to visible.	System	18 Jan 2021 16:25:26

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:40

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:40

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:40

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered empty.	System	18 Jan 2021 16:27:14
DataPoint set to visible.	System	18 Jan 2021 16:25:26

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '18 Jan 2021'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '10:00'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:14

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered '18 Jan 2021 10:00'	System	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '36.8' C	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:14

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered empty.	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '82'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:14

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered 'bpm'	System	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '14'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered 'breaths/min'	System	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '114'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered 'mmHg'	System	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '82'	(b) (4) Traci Hull (b) (4) (b) (4)	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered 'mmHg'	System	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:40

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:40

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:40

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered empty.	System	18 Jan 2021 16:27:14
DataPoint set to visible.	System	18 Jan 2021 16:25:26

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '18 Jan 2021'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '10:57'	(b) (4) Traci Hull (b) (4) (b) (4)	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered '18 Jan 2021 10:57'	System	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '36.5' C	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered empty.	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '72'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered 'bpm'	System	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '14'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered 'breaths/min'	System	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '112'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered 'mmHg'	System	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '70'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered 'mmHg'	System	18 Jan 2021 16:27:14

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:20

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '18 Jan 2021'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:20

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:43

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '18 Jan 2021'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:43

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Urine (URINE)'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:43

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Negative (NEGATIVE)'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:43

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:43

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered empty.	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:43

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered empty.	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:43

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered empty.	System	18 Jan 2021 16:27:43

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:58

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	18 Jan 2021 16:27:58

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered empty.	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:58

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered 'mRNA-1273'	System	18 Jan 2021 16:27:58
DataPoint set to visible.	System	18 Jan 2021 16:25:26

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '18 Jan 2021'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:58

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '10:25'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:58

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered '18 Jan 2021 10:25'	System	18 Jan 2021 16:27:58

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Left Arm (LEFT ARM)'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:27:58

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered 'ONCE'	System	18 Jan 2021 16:27:58

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered 'INTRAMUSCULAR'	System	18 Jan 2021 16:27:58

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:25:38

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '18 Jan 2021'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:25:38

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '09:47'	(b) (4) Traci Hull (b) (4) (b) (4)	18 Jan 2021 16:25:38

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered '18 Jan 2021 09:47'	System	18 Jan 2021 16:25:38

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:23:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:25:49

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:23:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '18 Jan 2021'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:25:49

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:23:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '09:49'	(b) (4) Traci Hull (b) (4) (b) (4)	18 Jan 2021 16:25:49

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:23:40

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered '18 Jan 2021 09:49'	System	18 Jan 2021 16:25:49

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	18 Jan 2021 16:25:54

US3402225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered '1'	System	18 Jan 2021 16:25:54

US3402225

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	26 Jan 2021 21:21:24

US3402225

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered '26 Jan 2021'	(b) (4) Tammy Kohn (b) (4)	26 Jan 2021 21:21:24
	(b) (4)	

US3402225

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Tammy Kohn (b) (4)	26 Jan 2021 21:21:24

US3402225

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered empty.	(b) (4) Tammy Kohn (b) (4)	26 Jan 2021 21:21:24
	(b) (4)	

US3402225

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	26 Jan 2021 21:21:27

US3402225

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered '1'	System	26 Jan 2021 21:21:27

US3402225

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered '1'	System	26 Jan 2021 21:21:27
DataPoint set to visible.	System	26 Jan 2021 21:21:27

US3402225

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:55:32

US3402225

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User closed query 'Per CDM re-query: Thank you for confirming the date is correct. Please clarify why the visit performed out of window in query response. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 05:54:36
Query 'Per CDM re-query: Thank you for confirming the date is correct. Please clarify why the visit performed out of window in query response. ' answered with 'VISIT PERFORMED OUT OF WINDOW DUE TO SUBJECT HAVING A RUPTURED APPENDIX. SUBJECT IS BACK ON TRACT NOW' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	12 Mar 2021 15:12:44
User closed query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	10 Mar 2021 05:29:24
User opened query 'Per CDM re-query: Thank you for confirming the date is correct. Please clarify why the visit performed out of window in query response. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 05:29:22
Query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' answered with 'CORRECT AS IS' (Site from System).	Traci Hull (b) (4) (b) (4)	09 Mar 2021 20:57:02
User opened query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	09 Mar 2021 20:55:32
User entered '09 Mar 2021'	Traci Hull (b) (4) (b) (4)	09 Mar 2021 20:55:32

US3402225

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Clinic (Clinic)'	(b) (4) Traci Hull (b) (4) (b) (4)	09 Mar 2021 20:55:32

US3402225

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered 'OLD29'	System	09 Mar 2021 20:55:32

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '09 Mar 2021'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '14:19'	(b) (4) Traci Hull (b) (4) (b) (4)	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered '09 Mar 2021 14:19'	System	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '36.7' C	(b) (4) Traci Hull (b) (4) (b) (4)	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered empty.	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '85'	(b) (4) Traci Hull (b) (4) (b) (4)	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered 'bpm'	System	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '14'	(b) (4) Traci Hull (b) (4) (b) (4)	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered 'breaths/min'	System	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '113'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered 'mmHg'	System	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '66'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered 'mmHg'	System	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '09 Mar 2021'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '15:34'	(b) (4) Traci Hull (b) (4) (b) (4)	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered '09 Mar 2021 15:34'	System	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '36.8' C	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered empty.	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '73'	(b) (4) Traci Hull (b) (4) (b) (4)	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered 'bpm'	System	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '14'	(b) (4) Traci Hull (b) (4) (b) (4)	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered 'breaths/min'	System	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '133'	(b) (4) Traci Hull (b) (4) (b) (4)	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered 'mmHg'	System	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '80'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered 'mmHg'	System	09 Mar 2021 20:58:27

US3402225

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:58:53

US3402225

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '09 Mar 2021'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:58:53

US3402225

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:59:18

US3402225

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '09 Mar 2021'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:59:18

US3402225

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Urine (URINE)'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:59:18

US3402225

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Negative (NEGATIVE)'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:59:18

US3402225

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:59:18

US3402225

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered empty.	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:59:18

US3402225

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered empty.	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:59:18

US3402225

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:23:40

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered empty.	System	09 Mar 2021 20:59:18

US3402225

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:59:52

US3402225

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered empty.	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:59:52

US3402225

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered empty.	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:59:52

US3402225

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered 'mRNA-1273'	System	09 Mar 2021 20:59:52
DataPoint set to visible.	System	26 Jan 2021 21:21:27

US3402225

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '09 Mar 2021'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:59:52

US3402225

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered '15:02'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:59:52

US3402225

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered '09 Mar 2021 15:02'	System	09 Mar 2021 20:59:52

US3402225

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Left Arm (LEFT ARM)'	(b) (4) Traci Hull (b) (4) (b) (4)	09 Mar 2021 20:59:52

US3402225

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered 'ONCE'	System	09 Mar 2021 20:59:52

US3402225

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:40

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered 'INTRAMUSCULAR'	System	09 Mar 2021 20:59:52

US3402225

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 20:59:59

US3402225

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered '1'	System	09 Mar 2021 20:59:59

US3402225

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	17 Mar 2021 16:39:02

US3402225

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered '17 Mar 2021'	(b) (4) Traci Hull (b) (4)	17 Mar 2021 16:39:02

US3402225

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	17 Mar 2021 16:39:02

US3402225

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered empty.	(b) (4) Traci Hull (b) (4)	17 Mar 2021 16:39:02

US3402225

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:49
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	17 Mar 2021 16:39:42

US3402225

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:08
User entered 'I'	System	17 Mar 2021 16:39:42

US3402225

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	05 Apr 2021 15:29:26
	(b) (4)	

US3402225

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
	(b) (4)	
User entered '5 Apr 2021'	Tammy Kohn (b) (4)	05 Apr 2021 15:29:26
	(b) (4)	

US3402225

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
	(b) (4)	
User entered 'Clinic (Clinic)'	Tammy Kohn (b) (4)	05 Apr 2021 15:29:26
	(b) (4)	

US3402225

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	05 Apr 2021 15:29:26

US3402225

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
	(b) (4)	
User entered 'No (N)'	Tammy Kohn (b) (4)	05 Apr 2021 15:29:41
	(b) (4)	

US3402225

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:51:12
User entered empty.	Tammy Kohn (b) (4) (b) (4)	05 Apr 2021 15:29:41

US3402225

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	05 Apr 2021 15:29:41
	(b) (4)	

US3402225

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 15:29:41

US3402225

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	05 Apr 2021 15:29:41
	(b) (4)	

US3402225

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	05 Apr 2021 15:29:41
	(b) (4)	

US3402225

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	05 Apr 2021 15:29:41
	(b) (4)	

US3402225

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	05 Apr 2021 15:29:41
	(b) (4)	

US3402225

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 15:29:41

US3402225

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	05 Apr 2021 15:29:41
	(b) (4)	

US3402225

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 15:29:41

US3402225

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	05 Apr 2021 15:29:41
	(b) (4)	

US3402225

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 15:29:41

US3402225

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	05 Apr 2021 15:29:41
	(b) (4)	

US3402225

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 15:29:41

US3402225

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
	(b) (4)	
User entered 'No (N)'	Tammy Kohn (b) (4)	05 Apr 2021 15:29:47
	(b) (4)	

US3402225

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	05 Apr 2021 15:29:47
	(b) (4)	

US3402225

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	05 Apr 2021 15:29:59
	(b) (4)	

US3402225

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
	(b) (4)	
User entered '5 Apr 2021'	Tammy Kohn (b) (4)	05 Apr 2021 15:29:59
	(b) (4)	

US3402225

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
	(b) (4)	
User entered '10:06'	Tammy Kohn (b) (4)	05 Apr 2021 15:29:59
	(b) (4)	

US3402225

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '5 Apr 2021 10:06'	System	05 Apr 2021 15:29:59

US3402225

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:23:40

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:42
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:43:58
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:40:25
User entered 'Yes (Y)' reason for change: New Information	(b) (4) Abigail Wine (b) (4)	18 Jan 2021 15:35:03
User entered 'No (N)'	Traci Hull (b) (4)	04 Sep 2020 13:03:21
	(b) (4)	

US3402225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:23:40

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41

US3402225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:23:40

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:19:34
User coded data point as SOC: Blood and lymphatic system disorders, HLG: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy axillary - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 15:00:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 15:00:21
User closed query 'Per DM CLR: Please review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY and ensure to provide the specific anatomical location and laterality of LYMPHADENOPATHY (e.g., Left Axillary Lymphadenopathy - IPSILATERAL to vaccination arm). Update accordingly. Otherwise, confirm that this is not Lymphadenopathy. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 04:17:04
Query 'Per DM CLR: Please review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY and ensure to provide the specific anatomical location and laterality of LYMPHADENOPATHY (e.g., Left Axillary Lymphadenopathy - IPSILATERAL to vaccination arm). Update accordingly. Otherwise, confirm that this is not Lymphadenopathy. ' answered with 'No Lymphadenopathy swelling was not in the Lymph nodes just under the arm itself. No further action needed the swelling went down overnight.' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	27 Jan 2021 15:03:31

US3402225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:23:40

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY and ensure to provide the specific anatomical location and laterality of LYMPHADENOPATHY (e.g., Left Axillary Lymphadenopathy - IPSILATERAL to vaccination arm). Update accordingly. Otherwise, confirm that this is not Lymphadenopathy. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 11:15:47
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Peripheral swelling, LLT: Swelling arm - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Jan 2021 15:38:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Jan 2021 15:38:06
Data point term sent to Coder	System	18 Jan 2021 15:37:10
User entered 'LEFT UNDERARM SWELLING'	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

US3402225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:23:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:19:37
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

US3402225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:23:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:19:42
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

US3402225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:23:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:19:43
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

US3402225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:23:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:19:45
User entered '28 Sep 2020'	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

US3402225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:23:40

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:19:47
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	18 Jan 2021 15:37:37
User entered empty; reason for change Per Query Resolution	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:37:37
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	18 Jan 2021 15:36:51
User entered '00:00'	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

US3402225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:23:40

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User entered empty.	System	18 Jan 2021 15:37:37
User entered '28 Sep 2020 00:00'	System	18 Jan 2021 15:36:51

US3402225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:23:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:19:49
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

US3402225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:23:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:19:51
User entered '29 Sep 2020'	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

US3402225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:23:40

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:19:53
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	18 Jan 2021 15:37:37
User entered empty; reason for change Per Query Resolution	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:37:37
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	18 Jan 2021 15:36:51
User entered '00:00'	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

US3402225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:23:40

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User entered empty.	System	18 Jan 2021 15:37:37
User entered '29 Sep 2020 00:00'	System	18 Jan 2021 15:36:51

US3402225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:23:40

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:19:55
User entered 'Grade 1/Mild (Grade 1/Mild)'	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

US3402225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:23:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:19:58
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

US3402225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:23:40

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:20:01
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

US3402225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:23:40

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:20:03
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

US3402225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:23:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:20:05
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:20:17
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:23:40

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:20:20
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:20:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:20:23
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:20:25
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:20:26
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:20:30
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:20:32
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Jan 2021 15:37:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Jan 2021 15:37:37
User entered 'Not Related (NOT RELATED)' reason for change: Per Query Resolution	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:37:37
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Jan 2021 15:36:51
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

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Folder: Adverse Events

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:20:33
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Jan 2021 15:37:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Jan 2021 15:37:37
User entered 'Not Related (NOT RELATED)' reason for change: Per Query Resolution	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:37:37
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Jan 2021 15:36:51
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

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Folder: Adverse Events

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:20:35
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Jan 2021 15:37:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Jan 2021 15:37:37
User entered 'None (NONE)' reason for change: Per Query Resolution	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:37:37
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Jan 2021 15:36:51
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:20:39
User entered '1'	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:23:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:20:41
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:20:42
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:20:44
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

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Folder: Adverse Events

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:20:47
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:20:50
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:36:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:23:40

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User entered '0'	System	18 Jan 2021 15:36:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:23:40

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41
User entered '1'	System	18 Jan 2021 15:36:51

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:16:41

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:22:15
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:52:25
User entered 'USA-US059-2021-mRNA-1273-P301000009'	System	12 Feb 2021 15:59:30
User entered 'New' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Feb 2021 15:59:30
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 15:57:33

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 15:52:25
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis perforated, LLT: Ruptured appendix - version MedDRA\23.0.	Coder Import (b) (4)	01 Mar 2021 15:53:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Mar 2021 15:53:51
Data point term sent to Coder	System	01 Mar 2021 15:52:34
Coding entries removed.	Jennifer Molstead (b) (4)	01 Mar 2021 15:52:18
	(b) (4)	
User entered 'Ruptured Appendix' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	01 Mar 2021 15:52:18
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\23.0.	Coder Import (b) (4)	11 Feb 2021 21:05:56
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Feb 2021 21:05:56
	(b) (4)	
Data point term sent to Coder	System	11 Feb 2021 21:04:44
User entered 'Appendicitis'	Jennifer Molstead (b) (4)	11 Feb 2021 21:04:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:52:25
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	11 Feb 2021 21:04:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:52:25
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	11 Feb 2021 21:04:10

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:52:25
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	11 Feb 2021 21:04:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:52:25
User entered '25 Jan 2021'	Jennifer Molstead (b) (4) (b) (4)	11 Feb 2021 21:04:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:40

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:52:25
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	11 Feb 2021 21:04:10

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Folder: Adverse Events

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 21:04:10

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Folder: Adverse Events

Form: Adverse Events (2)

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:52:25
User entered 'No (N)' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	03 Mar 2021 00:30:29
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	11 Feb 2021 21:04:10

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Folder: Adverse Events

Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:52:25
User entered '16 Feb 2021' reason for change: New Information	Jennifer Molstead (b) (4)	03 Mar 2021 00:30:29
User entered empty.	Jennifer Molstead (b) (4)	11 Feb 2021 21:04:10

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Folder: Adverse Events

Form: Adverse Events (2)

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End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:52:25
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	11 Feb 2021 21:04:10

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Folder: Adverse Events

Form: Adverse Events (2)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date, when available.?Please leave query open until information is available.' canceled (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 20:36:14
User opened query 'PV Query: Please provide the event end date, when available.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 16:51:55
User entered empty.	System	11 Feb 2021 21:04:10

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:52:25
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jennifer Molstead (b) (4) (b) (4)	11 Feb 2021 21:04:10

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:52:25
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	11 Feb 2021 21:04:10

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Folder: Adverse Events

Form: Adverse Events (2)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:52:25
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	11 Feb 2021 21:04:10

US3402225

Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:52:25
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	11 Feb 2021 21:04:10

US3402225

Folder: Adverse Events

Form: Adverse Events (2)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:52:25
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	15 Feb 2021 10:44:07
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject is still hospitalized' (Site from System).	Jennifer Molstead (b) (4) (b) (4)	11 Feb 2021 21:16:15
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	11 Feb 2021 21:04:10
User entered '1'	Jennifer Molstead (b) (4) (b) (4)	11 Feb 2021 21:04:10

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Folder: Adverse Events

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:52:25
User entered '8 Feb 2021'	Jennifer Molstead (b) (4) (b) (4)	11 Feb 2021 21:04:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:40

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4)	21 Apr 2021 15:52:25
	(b) (4), (b) (6)	
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 20:20:08
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'RECEIVED AND FAXED ' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 13:50:35
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 20:40:02
Query 'PV Query: Please provide discharge date in source.' canceled (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 20:37:22
User opened query 'PV Query: Please provide discharge date in source.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 15:56:03
User closed query 'Per CDM re-query: Response noted; Please provide discharge date once available. Please leave the query open till the update is made else respond to clarify. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 18:10:26
Query 'Per CDM re-query: Response noted; Please provide discharge date once available. Please leave the query open till the update is made else respond to clarify. ' answered with 'updated' (Site from DM).	Jennifer Molstead (b) (4) (b) (4)	01 Mar 2021 15:43:28
User entered '16 Feb 2021' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	01 Mar 2021 15:41:57

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[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User opened query 'Per CDM re-query: Response noted; Please provide discharge date once available. Please leave the query open till the update is made else respond to clarify. ' (Site from DM). User entered empty.	(b) (4), (b) (6)	15 Feb 2021 10:44:05
	Jennifer Molstead (b) (4)	11 Feb 2021 21:04:10

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Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:52:25
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	11 Feb 2021 21:04:10

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:52:25
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	11 Feb 2021 21:04:10

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:52:25
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	11 Feb 2021 21:04:10

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:52:25
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	11 Feb 2021 21:04:10

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:52:25
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	11 Feb 2021 21:04:10

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:52:25
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4) (b) (4)	11 Feb 2021 21:04:10

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:52:25
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4) (b) (4)	11 Feb 2021 21:04:10

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	03 May 2021 22:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:47:52
User closed query 'PV Query: As the subject had one dose of mRNA-1273 prior to event and received second dose of mRNA-1273 after event ended, action taken should not be not applicable. Please update action taken appropriately.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 14:22:06
Query 'PV Query: As the subject had one dose of mRNA-1273 prior to event and received second dose of mRNA-1273 after event ended, action taken should not be not applicable. Please update action taken appropriately.' answered with 'Dose was delayed slightly due to subject being in hospital, and subsequent recovery' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	29 Apr 2021 20:22:37
DataPoint Un-verified.	Jennifer Molstead (b) (4) (b) (4)	29 Apr 2021 20:21:43
Signature has been broken.	Jennifer Molstead (b) (4) (b) (4)	29 Apr 2021 20:21:43
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	29 Apr 2021 20:21:43
User opened query 'PV Query: As the subject had one dose of mRNA-1273 prior to event and received second dose of mRNA-1273 after event ended, action taken should not be not applicable. Please update action taken appropriately.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 18:49:02
User closed query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 18 Jan 2021), then event occurred. ' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 20:03:53
Query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 18 Jan 2021), then event occurred. ' answered with 'There is nothing I am able to change it to. my choices are None, dose delayed, investigational product withdrawn or not applicable.' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	28 Apr 2021 13:10:35

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Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 18 Jan 2021), then event occurred. ' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	28 Apr 2021 11:33:19
DataPoint Verified.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User closed query 'PV Query: As the last dose of study drug was given on 01 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 15:52:25
Query 'PV Query: As the last dose of study drug was given on 01 Sep 2020, please update the action taken with study drug from none to not applicable.'	(b) (4), (b) (6)	19 Apr 2021 20:20:15
answered with 'PER QUERY UPDATED TO NOT APPLICABLE' (Site from Safety).	Tammy Kohn (b) (4)	19 Apr 2021 13:40:20
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	(b) (4)	19 Apr 2021 13:39:47
User opened query 'PV Query: As the last dose of study drug was given on 01 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 20:39:08
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Feb 2021 21:15:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Feb 2021 21:15:52
User entered 'None (NONE)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	11 Feb 2021 21:15:52
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Feb 2021 21:04:10
User entered empty.	System	11 Feb 2021 21:04:10
	Jennifer Molstead (b) (4)	11 Feb 2021 21:04:10
	(b) (4)	

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:52:25
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	11 Feb 2021 21:04:10

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:52:25
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however the Concomitant medication that this AE is associated with started days after this AE has been resolved. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM). Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however the Concomitant medication that this AE is associated with started days after this AE has been resolved. Please review and add a Con Medication as appropriate or update action taken.' answered with 'SUBJECT REMAINED ON THE MEDICATIONS AFTER BEING DISCHARGED FROM THE HOSPITAL THEREFORE THE DATES WILL NOT MATCH' (Site from DM).	(b) (4), (b) (6) Tammy Kohn (b) (4) (b) (4)	21 Apr 2021 15:08:28 19 Apr 2021 13:45:30
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however the Concomitant medication that this AE is associated with started days after this AE has been resolved. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 17:18:16
Query 'Per DM: ConMed and ConProc are both checked on AE of Appendicitis; however, there is no matching indication given on ConMed or ConProc eCRFs. Please review and update as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 18:11:16
User opened query 'Per DM: ConMed and ConProc are both checked on AE of Appendicitis; however, there is no matching indication given on ConMed or ConProc eCRFs. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 21:56:31
User entered 'I'	Jennifer Molstead (b) (4) (b) (4)	11 Feb 2021 21:04:10

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:52:25
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic 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)	01 Mar 2021 18:11:09
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic 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).	Jennifer Molstead (b) (4) (b) (4)	01 Mar 2021 15:43:44
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic 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)	01 Mar 2021 07:18:17
User entered 'I'	Jennifer Molstead (b) (4) (b) (4)	11 Feb 2021 21:04:10

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:52:25
Query 'PV Query: Event outcome in EDC is not reflected in source. Also, If event has been resolved, please provide event end date.' canceled (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 20:37:29
User opened query 'PV Query: Event outcome in EDC is not reflected in source. Also, If event has been resolved, please provide event end date.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 15:50:37
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 15:50:37
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	03 Mar 2021 00:30:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	03 Mar 2021 00:30:29
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 16:52:27
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jennifer Molstead (b) (4) (b) (4)	11 Feb 2021 21:04:10

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:52:25
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	11 Feb 2021 21:04:10

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:52:25
User closed query 'PV Query: Laboratory results provided in case narrative were missing units. Please provide lab results with correct units.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 20:20:19
Query 'PV Query: Laboratory results provided in case narrative were missing units. Please provide lab results with correct units.' answered with 'UPDATED UNITS ON LAB RESULTS' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 13:50:47

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT PRESENTED AT EMERGENCY ROOM WITH ABDOMINAL PAIN SUBJECT HAD "ABDOMINAL SCAN" AND WAS DIAGNOSED WITH AN OVARIAN CYST. SUBJECT WAS PRESCRIBED PAIN MEDICATION AND SENT HOME. SUBJECT PRESENTED AT EMERGENCY ROOM 08FEB2021 WITH CONTINUING ABDOMINAL PAIN. SUBJECT AGAIN HAD A CT SCAN OF THE ABDOMEN. SHE WAS DETERMINED TO HAVE A RUPTURED APPENDIX. SUBJECT WAS TAKEN TO SURGERY WHERE HER APPENDIX AS WELL AS 5% OF HER LARGE AND SMALL INTESTINE WAS REMOVED. SUBJECT DID HAVE BLOOD WORK CONSISTING OF A BASIC METABOLIC PROFILE WITH THE FOLLOWING ABNORMAL LABS CRP 3.9, MG/DL NORMAL RANGE <0.9. MG/DL COMPLETE BLOOD COUNT WITH ABNORMAL VALUES OF WHITE BLOOD COUNT 13.3 NORMAL 4.0-10.5, RED BLOOD COUNT 3.26UL, NORMAL 4.0-5.20, HEMOGLOBIN 10.0G/DL NORMAL, 12.2-15.5, HEMATOCRIT 29.5 NORMAL, 35.0-47.0. SUBJECT TOLERATED SURGERY WELL. SE WAS GIVEN TYLENOL-CODINE 300-30 MG, LABS DRAWN ON11FEB2021 YIELDED A CRP OF 27.0, A WHITE BLOOD COUNT OF 16.7. AS STATED ABOVE SUBJECT HAS TOLERATED PROCEDURE WELL. SHE HAS BEEN DISCHARGED AND IS DOING THINGS AS TOLERATED.' reason for change: New Information	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 13:50:22
User opened query 'PV Query: Laboratory results provided in case narrative were missing units. Please provide lab results with correct units.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 20:38:20

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 17:25:38
User closed query 'PV Query: 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).' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 15:45:55
User closed query 'Per DM CLR: Narrative = SUBJECT WAS PRESCRIBED PAIN MEDICATION. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 05:08:02
Query 'Per DM CLR: Narrative = SUBJECT WAS PRESCRIBED PAIN MEDICATION. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	Jennifer Molstead (b) (4)	(b) (4) 03 Mar 2021 00:31:22
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	(b) (4) 03 Mar 2021 00:31:14
Query 'PV Query: 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).' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	(b) (4) 03 Mar 2021 00:31:07

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT PRESENTED AT EMERGENCY ROOM WITH ABDOMINAL PAIN SUBJECT HAD "ABDOMINAL SCAN" AND WAS DIAGNOSED WITH AN OVARIAN CYST. SUBJECT WAS PRESCRIBED PAIN MEDICATION AND SENT HOME. SUBJECT PRESENTED AT EMERGENCY ROOM 08FEB2021 WITH CONTINUING ABDOMINAL PAIN. SUBJECT AGAIN HAD a ct scan of the abdomen. she WAS DETERMINED TO HAVE A RUPTURED APPENDIX. SUBJECT WAS TAKEN TO SURGERY WHERE HER APPENDIX AS WELL AS 5% OF HER LARGE AND SMALL INTESTINE WAS REMOVED. Subject did have blood work consisting of a basic metabolic profile with the following abnormal labs CRP 3.9, Normal range <0.9. Complete blood count with abnormal values of White blood count 13.3 normal 4.0-10.5, red blood count 3.26, normal 4.0-5.20, hemoglobin 10.0 normal, 12.2-15.5, hematocrit 29.5 normal, 35.0-47.0. Subject Tolerated surgery well. Se was given Tylenol-Codine 300-30 mg, Labs drawn on 11feb2021 yielded a crp of 27.0, a white blood count of 16.7. As stated above subject has tolerated procedure well. She has been discharged and is doing things as tolerated.' reason for change: New Information	Jennifer Molstead (b) (4)	03 Mar 2021 00:28:52
User closed query 'IQVIA Medical query: - Please consider updating the event term to "Ruptured appendix." - Please confirm if ovarian cyst was one of the concurrent medical conditions for this subject. If yes, please add it to the medical history.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 15:47:46
User closed query 'PV Query: Please confirm if the initial abdominal scan diagnosed an ovarian cyst or if this was a misdiagnosis.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 15:47:42

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = SUBJECT WAS TAKEN TO SURGERY WHERE HER APPENDIX AS WELL AS 5% OF HER LARGE AND SMALL INTESTINE WAS REMOVED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 18:11:59
User closed query 'Per DM CLR: Narrative = SUBJECT AGAIN HAD AN "ABDOMINAL SCAN". However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 18:11:54
User closed query 'Per DM CLR: Narrative = DIAGNOSED WITH AN OVARIAN CYST. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 18:11:50
User closed query 'Per DM CLR: Narrative = SUBJECT HAD "ABDOMINAL SCAN". However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 18:11:45
Query 'Per DM CLR: Narrative = SUBJECT AGAIN HAD AN "ABDOMINAL SCAN". However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' answered with 'updated' (Site from DM).	Jennifer Molstead (b) (4)	(b) (4) 01 Mar 2021 16:07:48
Query 'Per DM CLR: Narrative = DIAGNOSED WITH AN OVARIAN CYST. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'This was a miss diagnosis' (Site from DM).	Jennifer Molstead (b) (4)	(b) (4) 01 Mar 2021 16:07:38
Query 'PV Query: Please confirm if the initial abdominal scan diagnosed an ovarian cyst or if this was a misdiagnosis.' answered with 'this was a misdiagnosis' (Site from Safety).	Jennifer Molstead (b) (4)	(b) (4) 01 Mar 2021 16:07:23

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Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = SUBJECT HAD "ABDOMINAL SCAN". However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' answered with 'updated' (Site from DM).	Jennifer Molstead (b) (4)	(b) (4) 01 Mar 2021 16:07:03
Query 'Per DM CLR: Narrative = SUBJECT WAS TAKEN TO SURGERY WHERE HER APPENDIX AS WELL AS 5% OF HER LARGE AND SMALL INTESTINE WAS REMOVED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' answered with 'UPdated' (Site from DM).	Jennifer Molstead (b) (4)	(b) (4) 01 Mar 2021 15:53:53
Query 'IQVIA Medical query: - Please consider updating the event term to "Ruptured appendix." - Please confirm if ovarian cyst was one of the concurrent medical conditions for this subject. If yes, please add it to the medical history.' answered with 'Updated' (Site from Safety).	Jennifer Molstead (b) (4)	(b) (4) 01 Mar 2021 15:52:48
User entered 'SUBJECT PRESENTED AT EMERGENCY ROOM WITH ABDOMINAL PAIN SUBJECT HAD "ABDOMINAL SCAN" AND WAS DIAGNOSED WITH AN OVARIAN CYST. SUBJECT WAS PRESCRIBED PAIN MEDICATION AND SENT HOME. SUBJECT PRESENTED AT EMERGENCY ROOM 08FEB2021 WITH CONTINUING ABDOMINAL PAIN. SUBJECT AGAIN HAD AN "ABDOMINAL SCAN" AND WAS DETERMINED TO HAVE A RUPTURED APPENDIX. SUBJECT WAS TAKEN TO SURGERY WHERE HER APPENDIX AS WELL AS 5% OF HER LARGE AND SMALL INTESTINE WAS REMOVED. SUBJECT IS STILL HOSIPTALIZED.' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	(b) (4) 01 Mar 2021 15:51:09
User opened query 'Per DM CLR: Narrative = SUBJECT WAS TAKEN TO SURGERY WHERE HER APPENDIX AS WELL AS 5% OF HER LARGE AND SMALL INTESTINE WAS REMOVED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 07:18:08

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = SUBJECT AGAIN HAD AN "ABDOMINAL SCAN". However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 07:18:03
User opened query 'Per DM CLR: Narrative = SUBJECT WAS PRESCRIBED PAIN MEDICATION. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 07:17:52
User opened query 'Per DM CLR: Narrative = DIAGNOSED WITH AN OVARIAN CYST. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 07:17:46
User opened query 'Per DM CLR: Narrative = SUBJECT HAD "ABDOMINAL SCAN". However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 07:17:32
User opened query 'IQVIA Medical query: - Please consider updating the event term to "Ruptured appendix." - Please confirm if ovarian cyst was one of the concurrent medical conditions for this subject. If yes, please add it to the medical history.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 16:56:04
User opened query 'PV Query: Please confirm if the initial abdominal scan diagnosed an ovarian cyst or if this was a misdiagnosis.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 16:54:57
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 16:54:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:40

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: 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).' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 16:53:14
User entered 'Subject presented at emergency room with abdominal pain subject had "abdominal scan" and was diagnosed with an ovarian cyst. Subject was prescribed pain medication and sent home. Subject presented at emergency room 08Feb2021 with continuing abdominal pain. Subject again had an "abdominal scan" and was determined to have a ruptured appendix. Subject was taken to surgery where her appendix as well as 5% of her large and small intestine was removed. Subject is still hospitalized. Awaiting medical Records for specifics.'	Jennifer Molstead (b) (4)	11 Feb 2021 21:04:10

US3402225

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:40

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	11 Feb 2021 21:04:10

US3402225

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:40

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	11 Feb 2021 21:04:10

US3402225

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:40

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Feb 2021 21:04:10

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:23:40

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:42
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:07:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:44:03
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' answered with 'SUBJECT STATED HAD BOTOX INJECTIONS FOR MIGRAINES' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 15:45:35
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 08:46:06
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:36:43

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS, PRODUCT: NORTRIPTYLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 12:39:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 12:39:12
Data point term sent to Coder User entered 'NORTRIPTYLINE'	System Tarin Gordon (b) (4)	05 Aug 2020 12:37:59 05 Aug 2020 12:37:34

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:40

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:37:34

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'MIGRAINES'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:37:34

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '10'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:37:34

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:40

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'mg (mg)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:37:34
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:40

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:37:34
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	(b) (4) System	05 Aug 2020 12:47:00
User entered 'other (OTHER)' reason for change: Data Entry Error	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:47:00
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	05 Aug 2020 12:37:34
User entered 'once (ONCE)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:37:34

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:40

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'BEDTIME'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:37:34

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:40

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Oral (ORAL)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:37:34
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:40

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:37:34

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:08:28
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 'ONGOING' (Site from System).	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:46:51
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	05 Aug 2020 12:37:34
User entered 'UN UNK 1983'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:37:34

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:37:34

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:37:34

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:37:34

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:37:34
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 12:37:34

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 12:37:34

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 12:37:34

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: CODEINE PHOSPHATE;PARACETAMOL, PRODUCTSYNONYM: TYLENOL W/CODEINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Aug 2020 13:10:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Aug 2020 13:10:11
Data point term sent to Coder	System	05 Aug 2020 12:40:01
User entered 'TYLENOL-CODEINE'	Tarin Gordon (b) (4)	05 Aug 2020 12:39:18

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:40

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:39:18

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'MIGRAINES'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:39:18

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '30/300'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:39:18

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:40

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'mg (mg)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:39:18
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:40

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:39:18
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'as needed (PRN)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:39:18

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:40

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:39:18
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:40

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Oral (ORAL)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:39:18

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:40

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:39:18

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:08:34
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:46:38
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	05 Aug 2020 12:39:18
User entered 'UN UNK 1983'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:39:18

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:40

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:39:18

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:39:18

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:39:18

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:39:18

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 12:39:18

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 12:39:18

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 12:39:18

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:40

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Aug 2020 12:41:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 12:41:17
Data point term sent to Coder User entered 'ZOLPIDEM'	System Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:40:01 05 Aug 2020 12:40:01

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:40

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:40:01
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'INSOMNIA'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:40:01

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '10'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:40:01

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:40

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'mg (mg)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:40:01
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:40

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:40:01
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'as needed (PRN)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:40:01
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:40

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:40:01
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:40

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Oral (ORAL)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:40:01
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:40

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:40:01

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:08:40
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 'ONGOING' (Site from System).	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:46:30
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 12:40:01
User entered 'UN UNK 2016'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:40:01

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:40:01

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:40:01
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:40:01

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:40:01

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 12:40:01

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 12:40:01

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 12:40:01

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE HYDROCHLORIDE, PRODUCTSYNONYM: TRAZODONE HCL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Aug 2020 23:32:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Aug 2020 23:32:21
Data point term sent to Coder	System	05 Aug 2020 12:41:04
User entered 'TRAZADONE HCL'	Tarin Gordon (b) (4)	05 Aug 2020 12:41:04

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:40

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:41:04

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
Query 'Per DM CLR: Please update the indication to reflect the location of MUSCLE SPASMS (e.g., Generalized, Both Legs, Right Arm, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 12:36:09
User opened query 'Per DM CLR: Please update the indication to reflect the location of MUSCLE SPASMS (e.g., Generalized, Both Legs, Right Arm, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 12:16:07
User entered 'MUSCLE SPASMS'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:41:04

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4)	07 Oct 2020 15:05:51
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4)	05 Oct 2020 19:57:36
User entered '25' reason for change: Data Entry Error	(b) (4)	05 Oct 2020 19:57:29
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 12:16:26
User entered '4'	Tarin Gordon (b) (4)	05 Aug 2020 12:41:04

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:40

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'mg (mg)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:41:04
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:40

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:41:04
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	(b) (4) System	05 Aug 2020 12:46:18
User entered 'other (OTHER)' reason for change: Data Entry Error	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:46:18
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	05 Aug 2020 12:41:04
User entered 'once (ONCE)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:41:04

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:40

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'BEDTIME'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:41:04
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:40

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Oral (ORAL)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:41:04
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:40

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:41:04

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:08:46
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 'ONGOING' (Site from System).	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:46:16
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	05 Aug 2020 12:41:04
User entered 'UN UNK 2018'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:41:04

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:41:04

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:41:04
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:41:04

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:41:04

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 12:41:04

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 12:41:04

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 12:41:04

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;HYDROCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 14:49:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 14:49:15
Data point term sent to Coder User entered	System Traci Hull (b) (4)	05 Aug 2020 16:20:25 05 Aug 2020 16:19:40
'HYDROCODONE-ACETAMINOPHEN' reason for change: Data Entry Error	(b) (4)	
Data point term sent to Coder User entered	System Tarin Gordon (b) (4)	05 Aug 2020 12:44:10 05 Aug 2020 12:43:11
'HYDROCODONE-ACETAMINOPHEN5/325'	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:40

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:43:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'LEFT SHOULDER PAIN'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:43:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '5/325'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:43:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:40

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'mg (mg)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:43:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:40

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:43:11
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'as needed (PRN)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:43:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:40

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:43:11
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:40

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Oral (ORAL)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:43:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:40

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:43:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:08:51
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 'ONGOING' (Site from System).	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:45:59
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	05 Aug 2020 12:43:11
User entered 'UN Mar 2020'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:43:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:40

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:43:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:43:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:43:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:43:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 12:43:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 12:43:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 12:43:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:23:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
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)	05 Aug 2020 12:45:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 12:45:21
Data point term sent to Coder User entered 'MAGNESIUM'	System Tarin Gordon (b) (4)	05 Aug 2020 12:44:11 05 Aug 2020 12:44:02

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:23:40

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:44:02

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:23:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'SUPPLEMENT'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:44:02

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:23:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '3'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:44:02

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:23:40

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'tablet (TABLET)'	(b) (4) Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:44:02

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:23:40

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:44:02
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:23:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'once daily (QD)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:44:02

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:23:40

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:44:02
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:23:40

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Oral (ORAL)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:44:02
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:23:40

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:44:02
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:23:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:08:56
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 'ONGOING' (Site from System).	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:45:53
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	05 Aug 2020 12:44:02
User entered 'UN UNK 2019'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:44:02

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:23:40

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:44:02

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:23:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:44:02

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:23:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:44:02

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:23:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:44:02

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:23:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 12:44:02

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:23:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 12:44:02

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:23:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 12:44:02

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:23:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Aug 2020 12:46:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 12:46:06
Data point term sent to Coder User entered 'MELATONIN'	System Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:45:13 05 Aug 2020 12:44:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:23:40

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:44:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:23:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'INSOMNIA'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:44:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:23:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '3'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:44:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:23:40

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'mg (mg)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:44:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:23:40

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:44:40
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:23:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	(b) (4) System	05 Aug 2020 12:45:40
User entered 'other (OTHER)' reason for change: Data Entry Error	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:45:40
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	05 Aug 2020 12:44:40
User entered 'once (ONCE)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:44:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:23:40

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'BEDTIME'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:44:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:23:40

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Oral (ORAL)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:44:40
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:23:40

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:44:40
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:23:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:09:02
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.' answered with 'ONGOING' (Site from System).	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:45:37
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 12:44:40
User entered 'UN UNK 2016'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:44:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:23:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:44:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:23:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:44:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:23:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:44:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:23:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:44:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:23:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 12:44:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:23:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 12:44:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:23:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 12:44:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:23:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
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)	05 Aug 2020 12:46:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Aug 2020 12:46:06
Data point term sent to Coder	System	05 Aug 2020 12:45:13
User entered 'MULTIVITAMIN'	Tarin Gordon (b) (4)	05 Aug 2020 12:45:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:23:40

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:45:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:23:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'SUPPLEMENT'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:45:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:23:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '1'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:45:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:23:40

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'tablet (TABLET)'	(b) (4) Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:45:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:23:40

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:45:11
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:23:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'twice daily (BID)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:45:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:23:40

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:45:11
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:23:40

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Oral (ORAL)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:45:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:23:40

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:45:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:23:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:09:07
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 'ONGOING' (Site from System).	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:45:21
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	05 Aug 2020 12:45:11
User entered 'UN UNK 2011'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:45:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:23:40

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:45:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:23:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:45:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:23:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:45:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:23:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 12:45:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:23:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Aug 2020 12:45:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:23:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 12:45:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:23:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 12:45:11

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:23:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
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.	(b) (4) Coder Import (b) (4) (b) (4)	18 Jan 2021 15:40:05
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 Jan 2021 15:40:05
Data point term sent to Coder	System	18 Jan 2021 15:39:10
User entered 'INFLUENZA VACCINE'	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:38:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:23:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Yes (Y)'	(b) (4) Abigail Wine (b) (4)	18 Jan 2021 15:38:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:23:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'INFLUENZA PROPHYLAXIS'	(b) (4) Abigail Wine (b) (4)	18 Jan 2021 15:38:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:23:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '0.5'	(b) (4) Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:38:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:23:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'mL (mL)'	(b) (4) Abigail Wine (b) (4)	18 Jan 2021 15:38:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:23:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Abigail Wine (b) (4)	18 Jan 2021 15:38:40
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:23:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'once (ONCE)'	(b) (4) Abigail Wine (b) (4)	18 Jan 2021 15:38:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:23:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Abigail Wine (b) (4)	18 Jan 2021 15:38:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:23:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:12
User entered 'Intramuscular (INTRAMUSCULAR)'	Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:38:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:23:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Abigail Wine (b) (4)	18 Jan 2021 15:38:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:23:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '28 Oct 2020'	(b) (4) Abigail Wine (b) (4)	18 Jan 2021 15:38:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:23:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '0'	(b) (4) Abigail Wine (b) (4) (b) (4)	18 Jan 2021 15:38:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:23:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'No (N)'	(b) (4) Abigail Wine (b) (4)	18 Jan 2021 15:38:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:23:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '28 Oct 2020'	(b) (4) Abigail Wine (b) (4)	18 Jan 2021 15:38:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:23:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'No (N)'	(b) (4) Abigail Wine (b) (4)	18 Jan 2021 15:38:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:23:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:46
User entered empty.	System	18 Jan 2021 15:38:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:23:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:46
User entered empty.	System	18 Jan 2021 15:38:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:23:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:46
User entered empty.	System	18 Jan 2021 15:38:40

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:23:40

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Mar 2021 07:37:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Mar 2021 07:37:01
Data point term sent to Coder	System	01 Mar 2021 16:00:43
User entered 'metranidazole'	Jennifer Molstead (b) (4)	01 Mar 2021 16:00:28

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:23:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'No (N)'	(b) (4) Jennifer Molstead (b) (4)	01 Mar 2021 16:00:28
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:23:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Ruptured appendix'	(b) (4) Jennifer Molstead (b) (4)	01 Mar 2021 16:00:28
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:23:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '500'	(b) (4) Jennifer Molstead (b) (4)	01 Mar 2021 16:00:28
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:23:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'mg (mg)'	(b) (4) Jennifer Molstead (b) (4)	01 Mar 2021 16:00:28
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:23:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:12
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	01 Mar 2021 16:00:28

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:23:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'three times daily (TID)'	(b) (4) Jennifer Molstead (b) (4)	01 Mar 2021 16:00:28
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:23:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:12
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	01 Mar 2021 16:00:28

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:23:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:12
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4) (b) (4)	01 Mar 2021 16:00:28

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:23:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:12
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	01 Mar 2021 16:00:28

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:23:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '25 Feb 2021'	(b) (4) Jennifer Molstead (b) (4)	01 Mar 2021 16:00:28
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:23:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '0'	(b) (4) Jennifer Molstead (b) (4)	01 Mar 2021 16:00:28
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:23:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 10:33:53
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'data updated' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	16 Mar 2021 19:50:39
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	16 Mar 2021 19:50:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	16 Mar 2021 19:48:35
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	16 Mar 2021 19:48:20
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 13:41:01
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	01 Mar 2021 16:00:28

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:23:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:12
User entered '08 Mar 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	16 Mar 2021 19:50:32
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	16 Mar 2021 19:48:35
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	16 Mar 2021 19:48:35
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	16 Mar 2021 19:48:20
User entered '16 Feb 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	16 Mar 2021 19:48:20
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	01 Mar 2021 16:00:28

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:23:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:12
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	01 Mar 2021 16:00:28

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:23:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:51
User entered '3'	System	01 Mar 2021 16:00:28

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:23:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:51
User entered '1'	System	01 Mar 2021 16:00:28

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:23:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:51
User entered '804 (804)'	System	01 Mar 2021 16:00:28

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:23:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Mar 2021 10:18:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 10:18:11
Data point term sent to Coder	System	01 Mar 2021 16:01:44
User entered 'ciprofloxacin'	Jennifer Molstead (b) (4) (b) (4)	01 Mar 2021 16:01:30

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:23:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:12
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	01 Mar 2021 16:01:30

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:23:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'ruptured appendix'	(b) (4) Jennifer Molstead (b) (4)	01 Mar 2021 16:01:30

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:23:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '500'	(b) (4) Jennifer Molstead (b) (4)	01 Mar 2021 16:01:30
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:23:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'mg (mg)'	(b) (4) Jennifer Molstead (b) (4)	01 Mar 2021 16:01:30
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:23:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:12
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	01 Mar 2021 16:01:30

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:23:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'twice daily (BID)'	(b) (4) Jennifer Molstead (b) (4)	01 Mar 2021 16:01:30
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:23:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:12
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	01 Mar 2021 16:01:30

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:23:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:12
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4) (b) (4)	01 Mar 2021 16:01:30

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:23:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Jennifer Molstead (b) (4)	01 Mar 2021 16:01:30
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:23:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '25 Feb 2021'	(b) (4) Jennifer Molstead (b) (4)	01 Mar 2021 16:01:30
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:23:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '0'	(b) (4) Jennifer Molstead (b) (4)	01 Mar 2021 16:01:30
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:23:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 10:34:35
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	16 Mar 2021 19:51:25
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	16 Mar 2021 19:51:16
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 13:41:09
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	01 Mar 2021 16:01:30

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:23:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:12
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	16 Mar 2021 19:51:16
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	16 Mar 2021 19:51:09
User entered '08 Mar 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	16 Mar 2021 19:51:09
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	01 Mar 2021 16:01:30

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:23:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:54:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'No (N)'	(b) (4) Jennifer Molstead (b) (4)	01 Mar 2021 16:01:30
	(b) (4)	

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:23:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:55
User entered '2'	System	01 Mar 2021 16:01:30

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:23:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:55
User entered '1'	System	01 Mar 2021 16:01:30

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:23:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:55
User entered '804 (804)'	System	01 Mar 2021 16:01:30

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:23:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:38:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:54:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 15:44:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 15:44:40
Data point term sent to Coder	System	19 Apr 2021 15:43:41
User entered 'BOTOX INJECTIONS'	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 15:43:21

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:23:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:38:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:54:39
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 15:43:21

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:23:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:38:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:54:39
User entered 'MIGRAINES'	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 15:43:21

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:23:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:38:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:54:39
User entered '5'	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 15:43:21

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:23:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:38:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:54:39
User entered 'IU (IU)'	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 15:43:21

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:23:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:38:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:54:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 15:43:21

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:23:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:38:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:54:39
User entered 'as needed (PRN)'	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 15:43:21

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:23:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:38:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:54:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 15:43:21

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:23:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:38:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:54:39
User entered 'Subcutaneous (SUBCUTANEOUS)'	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 15:43:21

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:23:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:38:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:54:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 15:43:21

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:23:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:38:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:54:39
User entered 'UN UNK 2019'	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 15:43:21

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:23:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:38:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:54:39
User entered '0'	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 15:43:21

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:23:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:38:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:54:39
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 15:43:21

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:23:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:38:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:54:39
User entered 'UN UNK 2019'	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 15:43:21

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:23:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:38:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:54:39
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 15:43:21

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:23:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:38:25
User entered empty.	System	19 Apr 2021 15:43:21

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:23:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:38:25
User entered empty.	System	19 Apr 2021 15:43:21

US3402225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:23:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:38:25
User entered empty.	System	19 Apr 2021 15:43:21

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:23:40

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:42
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:44:14
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Yes (Y)' reason for change: New Information	(b) (4) Jennifer Molstead (b) (4)	01 Mar 2021 15:42:03
User entered 'No (N)'	Traci Hull (b) (4)	04 Sep 2020 13:03:14

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:23:40

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '08 Feb 2021'	(b) (4) Jennifer Molstead (b) (4)	01 Mar 2021 15:42:56
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:23:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:12
User entered 'appendectomy'	Jennifer Molstead (b) (4) (b) (4)	01 Mar 2021 15:42:56

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:23:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4)	01 Mar 2021 15:42:56
	(b) (4)	

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:23:40

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:12
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	01 Mar 2021 15:42:56

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:23:40

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:14
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '08 Feb 2021'	(b) (4) Jennifer Molstead (b) (4)	01 Mar 2021 15:54:45
	(b) (4)	

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:23:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:14
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'CT Scan Abdomen'	(b) (4) Jennifer Molstead (b) (4)	01 Mar 2021 15:54:45
	(b) (4)	

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:23:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:14
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4)	01 Mar 2021 15:54:45
	(b) (4)	

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:23:40

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:14
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:12
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	01 Mar 2021 15:54:45

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:23:40

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:16
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '25 Jan 2021'	(b) (4) Jennifer Molstead (b) (4)	01 Mar 2021 15:55:30
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:23:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:16
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'CT SCAn abdomen'	(b) (4) Jennifer Molstead (b) (4)	01 Mar 2021 15:55:30

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:23:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:16
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4)	01 Mar 2021 15:55:30
	(b) (4)	

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:23:40

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:16
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:12
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	01 Mar 2021 15:55:30

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:23:40

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '8 Feb 2021'	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:33:22
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:23:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Complete Metabolic profile'	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:33:22
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:23:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:33:22
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:23:40

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:12
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Mar 2021 00:33:22

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:23:40

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '8 Feb 2021'	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:33:52
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:23:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'C-Reactive Protien'	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:33:52
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:23:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:33:52
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:23:40

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:12
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Mar 2021 00:33:52

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:23:40

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '8 Feb 2021'	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:34:23
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:23:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'complete blood count'	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:34:23
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:23:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:34:23
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:23:40

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:12
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Mar 2021 00:34:23

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:23:40

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:28
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '8 Feb 2021'	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:35:08
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:23:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:28
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'urinalysis'	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:35:08
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:23:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:28
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:12
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4) (b) (4)	03 Mar 2021 00:35:08

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:23:40

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:28
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:12
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Mar 2021 00:35:08

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:23:40

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '8 Feb 2021'	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:35:27
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:23:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'lipase'	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:35:27

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:23:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:35:27
	(b) (4)	

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:23:40

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:12
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Mar 2021 00:35:27

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:23:40

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:35
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '16 Feb 2021'	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:38:24
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:23:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:35
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'basic metabolic profile'	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:38:24
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:23:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:35
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:38:24
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:23:40

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:35
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:12
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Mar 2021 00:38:24

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 17:23:40

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '16 Feb 2021'	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:39:17
	(b) (4)	

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 17:23:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'complete blood count'	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:39:17

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 17:23:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:39:17
	(b) (4)	

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 17:23:40

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered empty.	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:39:17
	(b) (4)	

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 17:23:40

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '10 Feb 2021'	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:40:45
	(b) (4)	

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 17:23:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'basic metabolic profile'	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:40:45
	(b) (4)	

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 17:23:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:40:45
	(b) (4)	

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 17:23:40

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:12
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Mar 2021 00:40:45

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 17:23:40

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '10 Feb 2021'	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:41:34
	(b) (4)	

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 17:23:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'c reactive protien'	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:41:34
	(b) (4)	

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 17:23:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:41:34
	(b) (4)	

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 17:23:40

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:12
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Mar 2021 00:41:34

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 09 Jun 2021 17:23:40

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered '10 Feb 2021'	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:41:58
	(b) (4)	

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 09 Jun 2021 17:23:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'complete blood count'	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:41:58
	(b) (4)	

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 09 Jun 2021 17:23:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:32:12
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4)	03 Mar 2021 00:41:58
	(b) (4)	

US3402225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 09 Jun 2021 17:23:40

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:01:05
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:12
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Mar 2021 00:41:58

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'USA-US059-2021-MRNA-1273-P301000009'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Yes (Y)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Yes (Y)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Frank'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Eder'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered '1290 Upper Front Street'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Binghamton'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'NY'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered '13901'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:47:57
User entered 'US'	System	12 Feb 2021 16:00:47

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 14:22:42
User entered '5'	System	19 Apr 2021 20:20:47
User entered '4'	System	04 Mar 2021 16:22:46
User entered '3'	System	03 Mar 2021 17:33:07
User entered '2'	System	02 Mar 2021 15:48:08
User entered '1'	System	12 Feb 2021 16:00:47

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'USA-US059-2021-MRNA-1273-P301000009'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Yes (Y)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Yes (Y)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Frank'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Eder'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered '1290 Upper Front Street'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Binghamton'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'NY'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered '13901'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:47:57
User entered 'US'	System	12 Feb 2021 16:00:47

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 14:22:42
User entered '5'	System	19 Apr 2021 20:20:47
User entered '4'	System	04 Mar 2021 16:22:46
User entered '3'	System	03 Mar 2021 17:33:07
User entered '2'	System	02 Mar 2021 15:48:08
User entered '1'	System	12 Feb 2021 16:00:47

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:23:40

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
User entered '12/Feb/2021 11:00'	System	12 Feb 2021 16:00:47

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:23:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:47:57
User entered '1'	(b) (4), (b) (6)	12 Feb 2021 16:00:47

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'USA-US059-2021-MRNA-1273-P301000009'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Yes (Y)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Yes (Y)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Frank'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Eder'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered '1290 Upper Front Street'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Binghamton'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'NY'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered '13901'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:47:57
User entered 'US'	System	12 Feb 2021 16:00:47

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 14:22:42
User entered '5'	System	19 Apr 2021 20:20:47
User entered '4'	System	04 Mar 2021 16:22:46
User entered '3'	System	03 Mar 2021 17:33:07
User entered '2'	System	02 Mar 2021 15:48:08
User entered '1'	System	12 Feb 2021 16:00:47

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:23:40

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
User entered '02/Mar/2021 15:48'	System	02 Mar 2021 15:48:08

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:23:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 16:19:37
User entered '1'	(b) (4), (b) (6)	02 Mar 2021 15:48:08

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'USA-US059-2021-MRNA-1273-P301000009'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Yes (Y)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Yes (Y)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Frank'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Eder'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered '1290 Upper Front Street'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Binghamton'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'NY'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered '13901'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:47:57
User entered 'US'	System	12 Feb 2021 16:00:47

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 14:22:42
User entered '5'	System	19 Apr 2021 20:20:47
User entered '4'	System	04 Mar 2021 16:22:46
User entered '3'	System	03 Mar 2021 17:33:07
User entered '2'	System	02 Mar 2021 15:48:08
User entered '1'	System	12 Feb 2021 16:00:47

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:23:40

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
User entered '03/Mar/2021 12:33'	System	03 Mar 2021 17:33:07

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:23:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 16:19:37
User entered '1'	(b) (4), (b) (6)	03 Mar 2021 17:33:07

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'USA-US059-2021-MRNA-1273-P301000009'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Yes (Y)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Yes (Y)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Frank'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Eder'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered '1290 Upper Front Street'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Binghamton'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'NY'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered '13901'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:47:57
User entered 'US'	System	12 Feb 2021 16:00:47

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 14:22:42
User entered '5'	System	19 Apr 2021 20:20:47
User entered '4'	System	04 Mar 2021 16:22:46
User entered '3'	System	03 Mar 2021 17:33:07
User entered '2'	System	02 Mar 2021 15:48:08
User entered '1'	System	12 Feb 2021 16:00:47

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:23:40

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
User entered '04/Mar/2021 11:22'	System	04 Mar 2021 16:22:46

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:23:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 16:22:52
Un-reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 16:22:46
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 16:22:46
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 16:20:15
User entered '0'	(b) (4), (b) (6)	04 Mar 2021 16:20:03

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'USA-US059-2021-MRNA-1273-P301000009'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Yes (Y)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Yes (Y)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Frank'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Eder'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered '1290 Upper Front Street'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Binghamton'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'NY'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered '13901'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:47:57
User entered 'US'	System	12 Feb 2021 16:00:47

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 14:22:42
User entered '5'	System	19 Apr 2021 20:20:47
User entered '4'	System	04 Mar 2021 16:22:46
User entered '3'	System	03 Mar 2021 17:33:07
User entered '2'	System	02 Mar 2021 15:48:08
User entered '1'	System	12 Feb 2021 16:00:47

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:23:40

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
User entered '19/Apr/2021 13:20'	System	19 Apr 2021 20:20:47

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:23:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
User entered '1'	(b) (4), (b) (6)	19 Apr 2021 20:20:47

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'USA-US059-2021-MRNA-1273-P301000009'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Yes (Y)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Yes (Y)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'No (N)'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Frank'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Eder'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered '1290 Upper Front Street'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'Binghamton'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered 'NY'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:00:21
User entered '13901'	System	12 Feb 2021 15:59:30

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:55:06
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:47:57
User entered 'US'	System	12 Feb 2021 16:00:47

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 14:22:42
User entered '5'	System	19 Apr 2021 20:20:47
User entered '4'	System	04 Mar 2021 16:22:46
User entered '3'	System	03 Mar 2021 17:33:07
User entered '2'	System	02 Mar 2021 15:48:08
User entered '1'	System	12 Feb 2021 16:00:47

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:23:40

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	03 May 2021 22:58:18
User entered '30/Apr/2021 10:22'	(b) (4) System	30 Apr 2021 14:22:42

US3402225

Folder: SAE USA-US059-2021-MRNA-1273-P301000009

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:23:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	03 May 2021 22:58:18
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:22:42