

US3502125 (Prod: University of Colorado Hospital)

Generated By: KC Joubran

Generated On: 10 Jun 2021 07:56:49

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US3502125

Form: Participant Creation

Data signed: (b) (4) 16 Feb 2021 15:45:20

Generated On: 10 Jun 2021 07:56:49

[Participant ID](#)

US3502125

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

US3502125

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:45:21

Generated On: 10 Jun 2021 07:56:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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	SCRN

US3502125

Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Feb 2021 15:45:21

Generated On: 10 Jun 2021 07:56:49

Date of Birth (MMM yyyy)	(b) (6) 1970
Age	49
Age Units	YEARS
Age (Derived)	49
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	False
Black	True
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) 16 Feb 2021 15:45:21

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Date of Informed Consent (*dd MMM yyyy*) 09 SEP 2020

Month and Year of Informed Consent (derived) SEP 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) 16 Feb 2021 15:45:21

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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) 16 Feb 2021 15:45:21

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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) 16 Feb 2021 15:45:21

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Condition	TRANSIENT GLOBAL AMNESIA
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 16 Feb 2021 15:45:21

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Condition	GENERAL ACHES
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 15:45:21

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Were vital signs assessed? Yes
No

Date of assessment (*dd MMM yyyy*) 9 SEP 2020

Time of assessment (*00:00-23:59*) 14:48 (24 HR)

Vital Signs Date and Time (derived) 9 SEP 2020 14:48

Height (*xxx.x*) 159.8 cm

Weight (*xxx.x*) 104.5 lb

BMI (*xxx.x*) 18.60116 kg/m²

BMI units KG/M2

Temperature (*xxx.x*) ND - Not Done

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (*xxx*) ND - Not Done

Pulse units BPM

Respiratory Rate (*xxx*) ND - Not Done

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (*xxx*) ND - Not Done

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (*xxx*) 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) 16 Feb 2021 15:45:21

Generated On: 10 Jun 2021 07:56:49

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

9 SEP 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) 16 Feb 2021 15:45:21

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Date of assessment (*dd MMM yyyy*) 9 SEP 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) 16 Feb 2021 15:45:21

Generated On: 10 Jun 2021 07:56:49

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 9 SEP 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) 16 Feb 2021 15:45:21

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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) 16 Feb 2021 15:45:21

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:45:21

Generated On: 10 Jun 2021 07:56:49

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 09 SEP 2020

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

Folder OID VISIT1

US3502125

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 15:45:21

Generated On: 10 Jun 2021 07:56:49

What was the date of randomization? (dd MMM yyyy) 09 SEP 2020

What was the participant's randomization number? 112563

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

Human Immunodeficiency Virus (HIV) infection Yes No

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 15:45:21

Generated On: 10 Jun 2021 07:56:49

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 15:45:21

Generated On: 10 Jun 2021 07:56:49

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>)	9 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:55 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 13:55
Temperature (<i>xxx.x</i>)	97.3 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (<i>xxx</i>)	88 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	94 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 15:45:21

Generated On: 10 Jun 2021 07:56:49

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>)	9 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:20 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 15:20
Temperature (<i>xxx.x</i>)	97.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	96 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:45:21

Generated On: 10 Jun 2021 07:56:49

Was the physical examination performed?

Yes

No

Date of examination (*dd MMM yyyy*) _____

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 16 Feb 2021 15:45:21

Generated On: 10 Jun 2021 07:56:49

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) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 15:45:21

Generated On: 10 Jun 2021 07:56:49

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) 09 SEP 2020

What was the treatment time? (00:00-23:59) 14:49 (24 HR)

Treatment Date and Time (derived) 09 SEP 2020 14:49

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 15:45:21

Generated On: 10 Jun 2021 07:56:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	9 SEP 2020
Collection time (<i>00:00-23:59</i>)	14:35 (24 HR)
Collection date and time (derived)	9 SEP 2020 14:35

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 15:45:21

Generated On: 10 Jun 2021 07:56:49

Collection date (<i>dd MMM yyyy</i>)			9 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	14:45	9 SEP 2020 14:45
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:45:21

Generated On: 10 Jun 2021 07:56:49

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: 10 Jun 2021 07:56:49

TIMEPOINT

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.3 °F

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

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

PC Time Stamp 09 SEP 2020 15:14

PC Open Date & Time 09 SEP 2020 15:09

PC Close Date & Time 09 SEP 2020 17:39

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

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 96.5 °F

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

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

PC Time Stamp 09 SEP 2020 19:46
PC Open Date & Time 09 SEP 2020 18:34
PC Close Date & Time 10 SEP 2020 11:59

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:56:49

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	97.2 °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 SEP 2020 16:56
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:56:49

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	96.8 °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	11 SEP 2020 22:15
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes
No

Please record your **TEMPERATURE** in °F
Was any **MEDICATION TAKEN** today for pain or fever? Yes
No

Please confirm reason for pain or fever medication (may select more than one):
To **TREAT** pain or fever that has already occurred
To **PREVENT** pain or fever from occurring
PC Time Stamp
PC Open Date & Time 12 SEP 2020 12:00
PC Close Date & Time 13 SEP 2020 11:59

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:56:49

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	96.8 °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	13 SEP 2020 20:47
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:56:49

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	97.7 °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	15 SEP 2020 11:32
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.5 °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	15 SEP 2020 21:38
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

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

09 SEP 2020 15:14

PC Open Date & Time

09 SEP 2020 15:09

PC Close Date & Time

09 SEP 2020 17:39

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

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

09 SEP 2020 19:46

PC Open Date & Time

09 SEP 2020 18:34

PC Close Date & Time

10 SEP 2020 11:59

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:56:49

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

60

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

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

Please select one response below

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

PC Time Stamp	10 SEP 2020 18:47
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:56:49

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

50

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

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

Please select one response below

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

PC Time Stamp

11 SEP 2020 22:21

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:56:49

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

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

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

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

- Yes
- No

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

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

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

Please select one response below

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

PC Time Stamp

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:56:49

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

13 SEP 2020 20:48

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:56:49

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

15 SEP 2020 11:32

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:56:49

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

15 SEP 2020 21:38

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

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

No

Yes

PC Time stamp	09 SEP 2020 15:15
PC Open Date & Time	09 SEP 2020 15:09
PC Close Date & Time	09 SEP 2020 17:39

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

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

No

Yes

PC Time stamp	09 SEP 2020 19:47
PC Open Date & Time	09 SEP 2020 18:34
PC Close Date & Time	10 SEP 2020 11:59

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:56:49

	Yes <input type="checkbox"/>
PC Time stamp	10 SEP 2020 18:50
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:56:49

Yes

PC Time stamp

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:56:49

	Yes <input type="checkbox"/>
PC Time stamp	13 SEP 2020 20:48
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:56:49

	Yes <input type="checkbox"/>
PC Time stamp	15 SEP 2020 11:33
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:56:49

Yes

PC Time stamp

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3502125

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:45:21

Generated On: 10 Jun 2021 07:56:49

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 16 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3502125

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:45:21

Generated On: 10 Jun 2021 07:56:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3502125

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:45:20

Generated On: 10 Jun 2021 07:56:49

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 26 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3502125

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:45:20

Generated On: 10 Jun 2021 07:56:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3502125

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:45:20

Generated On: 10 Jun 2021 07:56:49

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 01 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3502125

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:45:20

Generated On: 10 Jun 2021 07:56:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3502125

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:46:38

Generated On: 10 Jun 2021 07:56:49

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 07 OCT 2020

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

Folder OID VISIT2

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 15:46:38

Generated On: 10 Jun 2021 07:56:49

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>)	07 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	13:55 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 13:55
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 15:46:38

Generated On: 10 Jun 2021 07:56:49

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 OCT 2020
Time of assessment (00:00-23:59)	15:08 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 15:08
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3502125

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:46:38

Generated On: 10 Jun 2021 07:56:49

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

07 OCT 2020

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

US3502125

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 16 Feb 2021 15:46:38

Generated On: 10 Jun 2021 07:56:49

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 07 OCT 2020

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

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

US3502125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 15:46:38

Generated On: 10 Jun 2021 07:56:49

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) 07 OCT 2020

What was the treatment time? (00:00-23:59) 14:37 (24 HR)

Treatment Date and Time (derived) 07 OCT 2020 14:37

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

US3502125

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 15:46:38

Generated On: 10 Jun 2021 07:56:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	07 OCT 2020
Collection time (<i>00:00-23:59</i>)	14:30 (24 HR)
Collection date and time (derived)	07 OCT 2020 14:30

US3502125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 15:45:21

Generated On: 10 Jun 2021 07:56:49

Collection date (<i>dd MMM yyyy</i>)			07 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:33	07 OCT 2020 14:33
Nasopharyngeal Swab 2	No		

US3502125

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:46:38

Generated On: 10 Jun 2021 07:56:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.3 °F

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

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

PC Time Stamp 07 OCT 2020 15:01

PC Open Date & Time 07 OCT 2020 14:57

PC Close Date & Time 07 OCT 2020 17:27

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

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 97.9 °F

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

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

PC Time Stamp 07 OCT 2020 19:25
PC Open Date & Time 07 OCT 2020 18:22
PC Close Date & Time 08 OCT 2020 11:59

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 99.3 °F

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

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

To **TREAT** pain or fever that has already occurred True

To **PREVENT** pain or fever from occurring False

PC Time Stamp 08 OCT 2020 15:11

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:56:49

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	97.9 °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	09 OCT 2020 18:08
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:56:49

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	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	11 OCT 2020 04:14
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:56:49

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	11 OCT 2020 21:16
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:56:49

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	97.9 °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	12 OCT 2020 17:15
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:56:49

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	97.5 °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	13 OCT 2020 21:26
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

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

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

07 OCT 2020 15:01

PC Open Date & Time

07 OCT 2020 14:57

PC Close Date & Time

07 OCT 2020 17:27

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp 07 OCT 2020 19:25

PC Open Date & Time 07 OCT 2020 18:22

PC Close Date & Time 08 OCT 2020 11:59

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:56:49

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	08 OCT 2020 15:12
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:56:49

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	09 OCT 2020 18:09
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:56:49

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

11 OCT 2020 04:14

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:56:49

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	11 OCT 2020 21:17
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:56:49

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	12 OCT 2020 17:15
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:56:49

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	13 OCT 2020 21:26
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

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

No

Yes

PC Time stamp	07 OCT 2020 15:02
PC Open Date & Time	07 OCT 2020 14:57
PC Close Date & Time	07 OCT 2020 17:27

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

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

No

Yes

PC Time stamp	07 OCT 2020 19:26
PC Open Date & Time	07 OCT 2020 18:22
PC Close Date & Time	08 OCT 2020 11:59

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:56:49

	Yes <input type="checkbox"/>
PC Time stamp	08 OCT 2020 15:14
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:56:49

	Yes <input type="checkbox"/>
PC Time stamp	09 OCT 2020 18:10
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:56:49

	Yes <input type="checkbox"/>
PC Time stamp	11 OCT 2020 04:15
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:56:49

	Yes <input type="checkbox"/>
PC Time stamp	11 OCT 2020 21:17
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:56:49

	Yes <input type="checkbox"/>
PC Time stamp	12 OCT 2020 17:16
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:56:49

	Yes <input type="checkbox"/>
PC Time stamp	13 OCT 2020 21:26
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3502125

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:45:21

Generated On: 10 Jun 2021 07:56:49

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3502125

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:45:20

Generated On: 10 Jun 2021 07:56:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3502125

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:45:21

Generated On: 10 Jun 2021 07:56:49

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3502125

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:45:21

Generated On: 10 Jun 2021 07:56:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3502125

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:45:21

Generated On: 10 Jun 2021 07:56:49

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 28 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3502125

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:45:21

Generated On: 10 Jun 2021 07:56:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3502125

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:46:38

Generated On: 10 Jun 2021 07:56:49

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 06 NOV 2020

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

Folder OID VISIT3

US3502125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 15:46:38

Generated On: 10 Jun 2021 07:56:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	06 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	10:09 (24 HR)
Vital Signs Date and Time (derived)	06 NOV 2020 10:09
Temperature (<i>xxx.x</i>)	36.2 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	95 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	96 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3502125

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:46:38

Generated On: 10 Jun 2021 07:56:49

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.

US3502125

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 15:46:38

Generated On: 10 Jun 2021 07:56:49

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 06 NOV 2020

Collection time (*00:00-23:59*) 10:25 (24 HR)

Collection date and time (derived) 06 NOV 2020 10:25

US3502125

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:46:38

Generated On: 10 Jun 2021 07:56:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

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 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

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 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 75

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 82

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 89

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

No

Yes

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

No

Yes

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

Date and time of submission 07 DEC 2020 07:26:38

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 DEC 2020 08:49:29
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 103

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

No

Yes

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

No

Yes

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

Date and time of submission 20 DEC 2020 12:14:29

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 DEC 2020 02:41:37
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 JAN 2021 00:49:45
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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	08 JAN 2021 21:40:31
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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	15 JAN 2021 21:32:47
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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 22 JAN 2021 04:02:36

Patient Cloud Open Date & Time 22 JAN 2021 00:01

Patient Cloud Close Date & Time 26 JAN 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 145

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

No

Yes

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

No

Yes

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

Date and time of submission 29 JAN 2021 08:53:09

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

Patient Cloud Close Date & Time 02 FEB 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 152

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

No

Yes

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

No

Yes

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

Date and time of submission 05 FEB 2021 08:27:18

Patient Cloud Open Date & Time 05 FEB 2021 00:01

Patient Cloud Close Date & Time 09 FEB 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 01:59:50
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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	21 FEB 2021 12:03:31
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 FEB 2021 07:28:29
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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	05 MAR 2021 07:59:42
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 187

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

No

Yes

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

No

Yes

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

Date and time of submission 12 MAR 2021 00:02:36

Patient Cloud Open Date & Time 12 MAR 2021 00:01

Patient Cloud Close Date & Time 16 MAR 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 MAR 2021 20:58:01
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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	29 MAR 2021 17:59:25
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 208

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

No

Yes

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

No

Yes

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

Date and time of submission 02 APR 2021 09:22:00

Patient Cloud Open Date & Time 02 APR 2021 00:01

Patient Cloud Close Date & Time 06 APR 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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	11 APR 2021 12:06:20
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	16 APR 2021 08:33:32
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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	26 APR 2021 00:35:44
Patient Cloud Open Date & Time	23 APR 2021 00:01
Patient Cloud Close Date & Time	27 APR 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 APR 2021 00:02:39
Patient Cloud Open Date & Time	30 APR 2021 00:01
Patient Cloud Close Date & Time	04 MAY 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 243

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 250

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 257

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 264

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 271

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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°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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 JUL 2021 00:01
Patient Cloud Close Date & Time	03 AUG 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

[Patient Cloud Close Date & Time](#) 17 AUG 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 AUG 2021 00:01
Patient Cloud Close Date & Time	24 AUG 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

[Patient Cloud Close Date & Time](#) 14 SEP 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 SEP 2021 00:01
Patient Cloud Close Date & Time	28 SEP 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Date and time of submission	
Patient Cloud Open Date & Time	08 OCT 2021 00:01
Patient Cloud Close Date & Time	12 OCT 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#) 19 OCT 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Date and time of submission	
Patient Cloud Open Date & Time	05 NOV 2021 00:01
Patient Cloud Close Date & Time	09 NOV 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Date and time of submission	
Patient Cloud Open Date & Time	12 NOV 2021 00:01
Patient Cloud Close Date & Time	16 NOV 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Date and time of submission	
Patient Cloud Open Date & Time	26 NOV 2021 00:01
Patient Cloud Close Date & Time	30 NOV 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Date and time of submission	
Patient Cloud Open Date & Time	03 DEC 2021 00:01
Patient Cloud Close Date & Time	07 DEC 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Date and time of submission	
Patient Cloud Open Date & Time	21 JAN 2022 00:01
Patient Cloud Close Date & Time	25 JAN 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Date and time of submission	
Patient Cloud Open Date & Time	28 JAN 2022 00:01
Patient Cloud Close Date & Time	01 FEB 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Date and time of submission	
Patient Cloud Open Date & Time	11 FEB 2022 00:01
Patient Cloud Close Date & Time	15 FEB 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Date and time of submission	
Patient Cloud Open Date & Time	18 FEB 2022 00:01
Patient Cloud Close Date & Time	22 FEB 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Date and time of submission	
Patient Cloud Open Date & Time	25 FEB 2022 00:01
Patient Cloud Close Date & Time	01 MAR 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#) 08 MAR 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Date and time of submission	
Patient Cloud Open Date & Time	11 MAR 2022 00:01
Patient Cloud Close Date & Time	15 MAR 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Date and time of submission	
Patient Cloud Open Date & Time	18 MAR 2022 00:01
Patient Cloud Close Date & Time	22 MAR 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Date and time of submission	
Patient Cloud Open Date & Time	25 MAR 2022 00:01
Patient Cloud Close Date & Time	29 MAR 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Date and time of submission	
Patient Cloud Open Date & Time	15 APR 2022 00:01
Patient Cloud Close Date & Time	19 APR 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 600

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 2022 00:01
Patient Cloud Close Date & Time	31 MAY 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 2022 00:01
Patient Cloud Close Date & Time	21 JUN 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

[Patient Cloud Close Date & Time](#) 12 JUL 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 2022 00:01
Patient Cloud Close Date & Time	19 JUL 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 2022 00:01
Patient Cloud Close Date & Time	02 AUG 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 2022 00:01
Patient Cloud Close Date & Time	09 AUG 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

[Patient Cloud Close Date & Time](#) 16 AUG 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 2022 00:01
Patient Cloud Close Date & Time	30 AUG 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 2022 00:01
Patient Cloud Close Date & Time	13 SEP 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 740

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 2022 00:01
Patient Cloud Close Date & Time	27 SEP 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

[Patient Cloud Close Date & Time](#) 18 OCT 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 2022 00:01
Patient Cloud Close Date & Time	08 NOV 2022 23:59

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

DAY 796

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

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

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

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

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

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

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

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

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 2022 00:01
Patient Cloud Close Date & Time	15 NOV 2022 23:59

US3502125

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 07:56:49

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		05 MAR 2021 07:59:50

US3502125

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:45:21

Generated On: 10 Jun 2021 07:56:49

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 3 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3502125

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:45:21

Generated On: 10 Jun 2021 07:56:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3502125

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:45:20

Generated On: 10 Jun 2021 07:56:49

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 7 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3502125

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:45:20

Generated On: 10 Jun 2021 07:56:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3502125

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:45:20

Generated On: 10 Jun 2021 07:56:49

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 03 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3502125

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:45:20

Generated On: 10 Jun 2021 07:56:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3502125

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 21:06:28

Generated On: 10 Jun 2021 07:56:49

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 06 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3502125

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 21:06:28

Generated On: 10 Jun 2021 07:56:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3502125

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 21:06:28

Generated On: 10 Jun 2021 07:56:49

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 05 APR 2021

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

Folder OID VISIT4

US3502125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 21:06:28

Generated On: 10 Jun 2021 07:56:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	05 APR 2021
Time of assessment (<i>00:00-23:59</i>)	12:55 (24 HR)
Vital Signs Date and Time (derived)	05 APR 2021 12:55
Temperature (<i>xxx.x</i>)	36.5 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	70 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3502125

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 21:06:28

Generated On: 10 Jun 2021 07:56:49

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

05 APR 2021

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

US3502125

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 21:06:28

Generated On: 10 Jun 2021 07:56:49

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 05 APR 2021

Collection time (*00:00-23:59*) 13:15 (24 HR)

Collection date and time (derived) 05 APR 2021 13:15

US3502125

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 21:06:28

Generated On: 10 Jun 2021 07:56:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3502125

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

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 _____

US3502125

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3502125

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:56:49

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"/>

US3502125

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 07:56:49

Generate Next COVID-19 Assessment

Yes

No

US3502125

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

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:45:20

Generated On: 10 Jun 2021 07:56:49

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 12 JAN 2021

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

Folder OID UNBLND_DECIDE

US3502125

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

Form: Unblinding

Data signed: (b) (4) 19 Mar 2021 19:43:10

Generated On: 10 Jun 2021 07:56:49

Date of updated informed consent (*dd MMM yyyy*) 12 JAN 2021

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

Was the participant unblinded? Yes
No

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

Date of unblinding (*dd MMM yyyy*) 12 JAN 2021

Participant randomization assignment mRNA-1273
Placebo

Actual Dose 1 mRNA-1273
Placebo
Not Administered

Actual Dose 2 mRNA-1273
Placebo
Not Administered

Will participant receive mRNA-1273? Yes
No

Placebo Only Flag _____

Continuing with mRNA-1273 _____

US3502125

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 15:45:20

Generated On: 10 Jun 2021 07:56:49

Was the sample collected? Yes No

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

Collection time (*00:00-23:59*) 14:17 (24 HR)

Collection date and time (derived) 12 JAN 2021 14:17

US3502125

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Feb 2021 15:45:20

Generated On: 10 Jun 2021 07:56:49

Was the sample collected? Yes No

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

Collection time (*00:00 - 23:59*) 14:24

Collection Date and Time (derived) 12 JAN 2021 14:24

US3502125

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 10:49:03

Generated On: 10 Jun 2021 07:56:49

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 10:49:03

Generated On: 10 Jun 2021 07:56:49

AEID USA-US080-2021-MRNA-1273-P30
1000001

Adverse event TRANSIENT GLOBAL AMNESIA

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) 09 APR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

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

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 09 APR 2021

Hospital Discharge Date (dd MMM yyyy) 10 APR 2021

Admitted to ICU? Yes
No
Unknown

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 10:49:03

Generated On: 10 Jun 2021 07:56:49

Number of Days in ICU	1
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>

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

Narrative

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 10:49:03

Generated On: 10 Jun 2021 07:56:49

STUDY STAFF WAS NOTIFIED
20APR2021, WE ARE
ATTEMPTING TO GATHER
MORE INFORMATION AT THIS
POINT. THIS AE REQUIRED A
TEMPORARY MEDICATION OF
LISINOPRIL. START DATES AND
END DATES MAY CHANGE.
ADDED 22APR2021
ON 20APR2021 SITE STAFF WAS
NOTIFIED BY SUBJECT THAT
SHE HAD A HOSPITAL
ADMISSION ON 09APR2021
THROUGH 10APR2021. SHE
STATES SHE WAS TAKEN TO
THE EMERGENCY
DEPARTMENT ON 09APR2021
BY HER HUSBAND AND WAS
ADMITTED TO THE ICU. HER
SYMPTOMS WERE
DISORIENTATION, NOT BEING
ABLE TO REMEMBER
ANYTHING, FOR ANY AMOUNT
OF TIME, AND UNABLE TO
FOLLOW SIMPLE
INSTRUCTIONS. SUBJECT ALSO
REPORTED THAT HER BLOOD
PRESSURE ON PRESENTATION
TO THE ED WAS 205/117 MMHG
WITH BLOOD PRESSURES
RETURNING TO NORMAL
PRIOR TO DISCHARGE. ED
VISIT DIFFERENTIAL
DIAGNOSIS CONSIDERED
INCLUDED BUT NOT LIMITED

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 10:49:03

Generated On: 10 Jun 2021 07:56:49

TO TIA, CVA, TRANSIENT
GLOBAL AMNESIA,
HYPERTENSIVE EMERGENCY,
ANXIETY. LAB RESULTS SHOW
NO LEUKOCYTOSIS OR
ANEMIA, NO SIGNIFICANT
ELECTROLYTE ABNORMALITY
OR RENAL FAILURE, HEART
NORMAL, TROPONIN
NEGATIVE. NO ARRHYTHMIA
ON EKG, CTA HEAD AND NECK
WITHOUT ACUTE
INTRACRANIAL PROCESS.
DURING THE HOSPITAL STAY,
SHE REGAINED THE ABILITY
TO REMEMBER, AND WAS
DISCHARGED ON 10APR2021.
SUBJECT HAS NO
RECOLLECTION OF HER BEING
BROUGHT TO THE ED OR
ADMISSION TO ICU. SHE WAS
PLACED ON LISINOPRIL 10MG
ONCE DAILY ON 13APR2021.
SHE VISITED HER PRIMARY
CARE PROVIDER 16APR2021,
AND HER LISINOPRIL WAS
DISCONTINUED. SHE STARTED
TAKING AMLODIPINE 5MG
ONCE DAILY ON 17APR2021.
TODAY, SHE REPORTS SHE HAS
SOME RESIDUAL MEMORY
ISSUES, SO THIS IS
CONSIDERED ONGOING. THE
CAUSE OF THE ADVERSE
EVENT IS UNDETERMINED,

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 10:49:03

Generated On: 10 Jun 2021 07:56:49

FURTHER TESTS WILL
INCLUDE A BRAIN MRI AND
KIDNEY ULTRASOUND. PER
THE PI, DR. THOMAS
CAMPBELL, MD, CAUSALITY
TO STUDY DRUG IS NOT
RELATED. MEDICAL RECORDS
ARE BEING REQUESTED.

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)	1

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Feb 2021 15:45:20

Generated On: 10 Jun 2021 07:56:49

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

Yes

No

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

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 10:49:03

Generated On: 10 Jun 2021 07:56:49

Name of Medication MIRENA

Prophylaxis Yes
No

Indication PREGNANCY PREVENTION

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify IUD

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 EVERY 6 YEARS

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 10:49:03

Generated On: 10 Jun 2021 07:56:49

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input checked="" 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

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 10:49:03

Generated On: 10 Jun 2021 07:56:49

Name of Medication MULTIVITAMIN

Prophylaxis Yes
No

Indication GENERAL WELLNESS

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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US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 10:49:03

Generated On: 10 Jun 2021 07:56:49

	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 2001

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

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 10:49:03

Generated On: 10 Jun 2021 07:56:49

Name of Medication IBUPROFEN

Prophylaxis Yes
No

Indication GENERAL ACHES

Dose per administration 600

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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) 28 Apr 2021 10:49:03

Generated On: 10 Jun 2021 07:56:49

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 2000

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

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 10:49:03

Generated On: 10 Jun 2021 07:56:49

Name of Medication TYLENOL

Prophylaxis Yes
No

Indication GENERAL ACHEs

Dose per administration 1000

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 10:49:03

Generated On: 10 Jun 2021 07:56:49

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 2000

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 10:49:03

Generated On: 10 Jun 2021 07:56:49

Name of Medication IBUPROFEN

Prophylaxis Yes
No

Indication HEADACHE, MYALGIA PER
DIARY

Dose per administration 200

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

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 10:49:03

Generated On: 10 Jun 2021 07:56:49

	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) 8 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 8 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

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 10:49:03

Generated On: 10 Jun 2021 07:56:49

Name of Medication ACETAMINOPHEN

Prophylaxis Yes
No

Indication HEADACHE, MYALGIA PER
DIARY

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

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) 28 Apr 2021 10:49:03

Generated On: 10 Jun 2021 07:56:49

	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) 8 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 8 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

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 10:49:03

Generated On: 10 Jun 2021 07:56:49

Name of Medication NAPROXEN

Prophylaxis Yes
No

Indication HEADACHE, MYALGIA PER
DIARY

Dose per administration 220

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

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 10:49:03

Generated On: 10 Jun 2021 07:56:49

	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) 8 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 8 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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 10:49:03

Generated On: 10 Jun 2021 07:56:49

Name of Medication FLU VACCINE

Prophylaxis Yes
No

Indication FLU PREVENTION

Dose per administration 0.5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 10:49:03

Generated On: 10 Jun 2021 07:56:49

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*) 29 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 29 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

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 10:49:03

Generated On: 10 Jun 2021 07:56:49

Name of Medication LISINOPRIL

Prophylaxis Yes
No

Indication TRANSIENT GLOBAL AMNESIA

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 (9)

Data signed: (b) (4) 28 Apr 2021 10:49:03

Generated On: 10 Jun 2021 07:56:49

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*) 13 APR 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 16 APR 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 10:49:03

Generated On: 10 Jun 2021 07:56:49

Name of Medication AMLODIPINE

Prophylaxis Yes
No

Indication TRANSIENT GLOBAL AMNESIA

Dose per administration 5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 10:49:03

Generated On: 10 Jun 2021 07:56:49

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

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 17 APR 2021

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3502125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 10:49:03

Generated On: 10 Jun 2021 07:56:49

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3502125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 28 Apr 2021 10:49:03

Generated On: 10 Jun 2021 07:56:49

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
09 APR 2021	EKG	Adverse Event	
09 APR 2021	CTA HEAD AND NECK	Adverse Event	

US3502125

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 07:56:49

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

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 10:49:04

Generated On: 10 Jun 2021 07:56:49

SAEID	USA-US080-2021-MRNA-1273-P30 1000001
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	THOMAS
Investigator's Last Name	CAMPBELL
Site Address: Street	
Site Address: City	
Site Address: State	CO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 10:49:04

Generated On: 10 Jun 2021 07:56:49

SAEID	USA-US080-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	THOMAS
Investigator's Last Name	CAMPBELL
Site Address: Street	
Site Address: City	
Site Address: State	CO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	22/APR/2021 06:33
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.	<input checked="" type="checkbox"/> True

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 10:49:04

Generated On: 10 Jun 2021 07:56:49

SAEID	USA-US080-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	THOMAS
Investigator's Last Name	CAMPBELL
Site Address: Street	
Site Address: City	
Site Address: State	CO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	23/APR/2021 07:40
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.	True

Audit

US3502125 (Prod: University of Colorado Hospital)

US3502125

Form: Participant Creation

Generated On: 10 Jun 2021 07:56:49

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'US3502125'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 20:24:37

US3502125

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:56:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:25:07

US3502125

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '09 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 20:24:38

US3502125

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:25:07

US3502125

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:56:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User entered 'SCRN'	System	09 Sep 2020 20:25:07

US3502125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:56:49

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered (b) (6) 1970'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 20:24:39

US3502125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:56:49

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '49'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:25:30

US3502125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:56:49

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User entered 'YEARS'	System	09 Sep 2020 20:25:30

US3502125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:56:49

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User entered '49'	System	09 Sep 2020 20:26:18

US3502125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:56:49

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:25:30

US3502125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:56:49

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:25:30

US3502125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:56:49

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:25:30

US3502125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:56:49

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '1'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:25:30

US3502125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:56:49

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:25:30

US3502125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:56:49

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:25:30

US3502125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:56:49

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:25:30

US3502125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:56:49

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:25:30

US3502125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:56:49

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:25:30

US3502125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:56:49

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:25:30

US3502125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:56:49

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:25:30

US3502125

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:56:49

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '09 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:26:18

US3502125

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User entered 'Sep 2020'	System	09 Sep 2020 20:26:18

US3502125

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User entered '2020'	System	09 Sep 2020 20:26:18

US3502125

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:56:49

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:26:18

US3502125

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:26:18

US3502125

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:56:49

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:26:18

US3502125

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:56:49

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:26:18

US3502125

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:56:49

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:26:18

US3502125

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:56:49

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 20:24:38

US3502125

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:56:49

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User entered '1'	System	09 Sep 2020 20:26:33

US3502125

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:26:33

US3502125

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 07:56:49

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Josie Marshall (b) (4)	11 Sep 2020 19:54:20

US3502125

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:56:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User coded data point as SOC: Nervous system disorders, HLGT: Mental impairment disorders, HLT: Memory loss (excl dementia), PT: Transient global amnesia, LLT: Transient global amnesia - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	11 Sep 2020 19:56:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Sep 2020 19:56:47
Data point term sent to Coder	System	11 Sep 2020 19:55:22
User entered 'transient global amnesia'	Josie Marshall (b) (4)	11 Sep 2020 19:55:21

US3502125

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'un UNK 2015'	Josie Marshall (b) (4)	11 Sep 2020 19:55:21

US3502125

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:56:49

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '0'	Josie Marshall (b) (4)	11 Sep 2020 19:55:21

US3502125

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:56:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'No (N)'	Josie Marshall (b) (4)	11 Sep 2020 19:55:21

US3502125

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'un UNK 2015'	Josie Marshall (b) (4)	11 Sep 2020 19:55:21

US3502125

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:56:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '0'	Josie Marshall (b) (4)	11 Sep 2020 19:55:21

US3502125

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:56:49

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User entered 'Jan 2015'	System	11 Sep 2020 19:55:21

US3502125

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:56:49

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User entered '2015'	System	11 Sep 2020 19:55:21

US3502125

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User entered 'Jan 2015'	System	11 Sep 2020 19:55:21

US3502125

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User entered '2015'	System	11 Sep 2020 19:55:21

US3502125

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:56:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: Generalized aching - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 21:40:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 21:40:54
Data point term sent to Coder	System	02 Dec 2020 21:40:41
User entered 'General aches'	(b) (4), (b) (6)	02 Dec 2020 21:40:10

US3502125

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'UN UNK 2000'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:40:10

US3502125

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:56:49

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:40:10

US3502125

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:56:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:40:10

US3502125

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:40:10

US3502125

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:56:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:40:10

US3502125

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:56:49

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User entered 'Jan 2000'	System	02 Dec 2020 21:40:10

US3502125

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User entered '2000'	System	02 Dec 2020 21:40:10

US3502125

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User entered empty.	System	02 Dec 2020 21:40:10

US3502125

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User entered empty.	System	02 Dec 2020 21:40:10

US3502125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Josie Marshall (b) (4)	11 Sep 2020 20:42:41

US3502125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '9 Sep 2020'	Josie Marshall (b) (4)	11 Sep 2020 20:42:41

US3502125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '14:48'	Josie Marshall (b) (4)	11 Sep 2020 20:42:41

US3502125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User entered '9 Sep 2020 14:48'	System	11 Sep 2020 20:42:41

US3502125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '159.8' cm	(b) (4) Josie Marshall (b) (4)	11 Sep 2020 20:42:41
DataPoint set to visible.	(b) (4) System	09 Sep 2020 20:26:33

US3502125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '104.5' lb	(b) (4) Josie Marshall (b) (4)	11 Sep 2020 20:42:41
DataPoint set to visible.	(b) (4) System	09 Sep 2020 20:26:33

US3502125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User entered '18.60116'	System	11 Sep 2020 20:42:41
DataPoint set to visible.	System	09 Sep 2020 20:26:33

US3502125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User entered 'kg/m2'	System	11 Sep 2020 20:42:41
DataPoint set to visible.	System	09 Sep 2020 20:26:33

US3502125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered missing code ND - Not Done.	Josie Marshall (b) (4)	11 Sep 2020 20:42:41

US3502125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	Josie Marshall (b) (4)	11 Sep 2020 20:42:41

US3502125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	Josie Marshall (b) (4)	11 Sep 2020 20:42:41

US3502125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered missing code ND - Not Done.	Josie Marshall (b) (4)	11 Sep 2020 20:42:41

US3502125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User entered 'bpm'	System	11 Sep 2020 20:42:41

US3502125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered missing code ND - Not Done.	Josie Marshall (b) (4)	11 Sep 2020 20:42:41

US3502125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User entered 'breaths/min'	System	11 Sep 2020 20:42:41

US3502125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered missing code ND - Not Done.	Josie Marshall (b) (4)	11 Sep 2020 20:42:41

US3502125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User entered 'mmHg'	System	11 Sep 2020 20:42:41

US3502125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered missing code ND - Not Done.	Josie Marshall (b) (4)	11 Sep 2020 20:42:41

US3502125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User entered 'mmHg'	System	11 Sep 2020 20:42:41

US3502125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53

US3502125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53

US3502125

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 07:56:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Josie Marshall (b) (4)	11 Sep 2020 20:43:04

US3502125

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 07:56:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '9 Sep 2020'	Josie Marshall (b) (4)	11 Sep 2020 20:43:04

US3502125

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:56:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '9 Sep 2020'	Josie Marshall (b) (4)	11 Sep 2020 20:43:21

US3502125

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:56:49

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Josie Marshall (b) (4)	11 Sep 2020 20:43:21

US3502125

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:56:49

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	Josie Marshall (b) (4)	11 Sep 2020 20:43:21

US3502125

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:56:49

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	Josie Marshall (b) (4)	11 Sep 2020 20:43:21

US3502125

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	Josie Marshall (b) (4)	11 Sep 2020 20:43:21

US3502125

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:56:49

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '0'	Josie Marshall (b) (4)	11 Sep 2020 20:43:21

US3502125

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	Josie Marshall (b) (4)	11 Sep 2020 20:43:21

US3502125

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:56:49

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '0'	Josie Marshall (b) (4)	11 Sep 2020 20:43:21

US3502125

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:49

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Josie Marshall (b) (4)	11 Sep 2020 20:43:45

US3502125

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:49

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '9 Sep 2020'	Josie Marshall (b) (4)	11 Sep 2020 20:43:45

US3502125

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:49

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Urine (URINE)'	Josie Marshall (b) (4)	11 Sep 2020 20:43:45

US3502125

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:49

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Negative (NEGATIVE)'	Josie Marshall (b) (4)	11 Sep 2020 20:43:45

US3502125

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:49

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'No (N)'	Josie Marshall (b) (4)	11 Sep 2020 20:43:45

US3502125

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:49

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	Josie Marshall (b) (4)	11 Sep 2020 20:43:45

US3502125

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:49

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	Josie Marshall (b) (4)	11 Sep 2020 20:43:45

US3502125

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:49

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User entered empty.	System	11 Sep 2020 20:43:45

US3502125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Josie Marshall (b) (4)	11 Sep 2020 20:44:11

US3502125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'No (N)'	Josie Marshall (b) (4)	11 Sep 2020 20:44:11

US3502125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'No (N)'	Josie Marshall (b) (4)	11 Sep 2020 20:44:11

US3502125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'No (N)'	Josie Marshall (b) (4)	11 Sep 2020 20:44:11

US3502125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:49

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'No (N)'	Josie Marshall (b) (4)	11 Sep 2020 20:44:11

US3502125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'No (N)'	Josie Marshall (b) (4)	11 Sep 2020 20:44:11

US3502125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'No (N)'	Josie Marshall (b) (4)	11 Sep 2020 20:44:11

US3502125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'No (N)'	Josie Marshall (b) (4)	11 Sep 2020 20:44:11

US3502125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'No (N)'	Josie Marshall (b) (4)	11 Sep 2020 20:44:11

US3502125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'No (N)'	Josie Marshall (b) (4)	11 Sep 2020 20:44:11

US3502125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'No (N)'	Josie Marshall (b) (4)	11 Sep 2020 20:44:11

US3502125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:49

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'No (N)'	Josie Marshall (b) (4)	11 Sep 2020 20:44:11

US3502125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:49

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	Josie Marshall (b) (4)	11 Sep 2020 20:44:11

US3502125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:49

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '0'	Josie Marshall (b) (4)	11 Sep 2020 20:44:11

US3502125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:49

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '0'	Josie Marshall (b) (4)	11 Sep 2020 20:44:11

US3502125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '0'	Josie Marshall (b) (4)	11 Sep 2020 20:44:11

US3502125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '0'	Josie Marshall (b) (4)	11 Sep 2020 20:44:11

US3502125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '0'	Josie Marshall (b) (4)	11 Sep 2020 20:44:11

US3502125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '1'	Josie Marshall (b) (4)	11 Sep 2020 20:44:11

US3502125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:49

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '0'	Josie Marshall (b) (4)	11 Sep 2020 20:44:11

US3502125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:49

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	Josie Marshall (b) (4)	11 Sep 2020 20:44:11

US3502125

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:56:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:35:09

US3502125

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:56:49

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '09 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:35:09

US3502125

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:35:09

US3502125

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:56:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered 'VISIT1'	System	09 Sep 2020 20:35:09

US3502125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '09 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 20:24:44

US3502125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:56:49

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '112563'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 20:24:44

US3502125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 20:24:44

US3502125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:56:49

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)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:35:20

US3502125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:56:49

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)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:35:20

US3502125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:35:20

US3502125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:56:49

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:35:20

US3502125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:56:49

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:35:20

US3502125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:56:49

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User closed query 'Per CDM: This field requires a Yes or No response. Please complete. (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 07:43:45
Query 'Per CDM: This field requires a Yes or No response. Please complete. answered with 'Done' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 21:21:14
User entered 'No (N)'	(b) (4), (b) (6)	07 Dec 2020 21:21:09
User opened query 'Per CDM: This field requires a Yes or No response. Please complete. (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 19:35:27
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:53:28
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:53:27

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:56:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered missing code ND - Not Done.	Josie Marshall (b) (4)	11 Sep 2020 20:44:59

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:56:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered missing code ND - Not Done.	Josie Marshall (b) (4)	11 Sep 2020 20:44:59

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:56:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered missing code ND - Not Done.	Josie Marshall (b) (4)	11 Sep 2020 20:44:59

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:56:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered missing code ND - Not Done.	Josie Marshall (b) (4)	11 Sep 2020 20:44:59

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User accepted default value 'Pre-Dose (PREDOSE)'	Josie Marshall (b) (4) (b) (4)	11 Sep 2020 20:44:59

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Josie Marshall (b) (4)	11 Sep 2020 20:44:59

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '9 Sep 2020'	Josie Marshall (b) (4)	11 Sep 2020 20:44:59

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '13:55'	Josie Marshall (b) (4)	11 Sep 2020 20:44:59

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered '9 Sep 2020 13:55'	System	11 Sep 2020 20:44:59

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '97.3' F	Josie Marshall (b) (4)	11 Sep 2020 20:44:59

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Other (Other)'	Josie Marshall (b) (4)	11 Sep 2020 20:44:59

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'forehead'	Josie Marshall (b) (4)	11 Sep 2020 20:44:59

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '88'	Josie Marshall (b) (4)	11 Sep 2020 20:44:59

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered 'bpm'	System	11 Sep 2020 20:44:59

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '14'	Josie Marshall (b) (4)	11 Sep 2020 20:44:59

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered 'breaths/min'	System	11 Sep 2020 20:44:59

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '138'	Josie Marshall (b) (4)	11 Sep 2020 20:44:59

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered 'mmHg'	System	11 Sep 2020 20:44:59

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '94'	Josie Marshall (b) (4)	11 Sep 2020 20:44:59

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered 'mmHg'	System	11 Sep 2020 20:44:59

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:56:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered missing code ND - Not Done.	Josie Marshall (b) (4)	11 Sep 2020 20:44:59

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:56:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered missing code ND - Not Done.	Josie Marshall (b) (4)	11 Sep 2020 20:44:59

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User accepted default value 'Post-Dose (POSTDOSE)'	Josie Marshall (b) (4) (b) (4)	11 Sep 2020 20:45:54

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Josie Marshall (b) (4)	11 Sep 2020 20:45:54

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '9 Sep 2020'	Josie Marshall (b) (4)	11 Sep 2020 20:45:54

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '15:20'	Josie Marshall (b) (4)	11 Sep 2020 20:45:54

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered '9 Sep 2020 15:20'	System	11 Sep 2020 20:45:54

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '97.1' F	Josie Marshall (b) (4)	11 Sep 2020 20:45:54

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Other (Other)'	Josie Marshall (b) (4)	11 Sep 2020 20:45:54

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'forehead'	Josie Marshall (b) (4)	11 Sep 2020 20:45:54

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '76'	Josie Marshall (b) (4)	11 Sep 2020 20:45:54

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered 'bpm'	System	11 Sep 2020 20:45:54

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '16'	Josie Marshall (b) (4)	11 Sep 2020 20:45:54

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered 'breaths/min'	System	11 Sep 2020 20:45:54

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '140'	Josie Marshall (b) (4)	11 Sep 2020 20:45:54

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered 'mmHg'	System	11 Sep 2020 20:45:54

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '96'	Josie Marshall (b) (4)	11 Sep 2020 20:45:54

US3502125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered 'mmHg'	System	11 Sep 2020 20:45:54

US3502125

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 07:56:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'No (N)'	Josie Marshall (b) (4)	11 Sep 2020 20:46:01

US3502125

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 07:56:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	Josie Marshall (b) (4)	11 Sep 2020 20:46:01

US3502125

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:49

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'No (N)'	Josie Marshall (b) (4)	11 Sep 2020 20:46:09

US3502125

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:49

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	Josie Marshall (b) (4)	11 Sep 2020 20:46:09

US3502125

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:49

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	Josie Marshall (b) (4)	11 Sep 2020 20:46:09

US3502125

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:49

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	Josie Marshall (b) (4)	11 Sep 2020 20:46:09

US3502125

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:49

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User closed query 'Per CDM: Please consider entering data as No.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 04:41:55
' (Site from DM). Query 'Per CDM: Please consider entering data as No.	(b) (4), (b) (6)	07 Dec 2020 21:25:19
' answered with 'Done' (Site from DM). User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 21:25:14
User opened query 'Per CDM: Please consider entering data as No.	(b) (4), (b) (6)	04 Dec 2020 12:32:50
' (Site from DM). User entered empty.	Josie Marshall (b) (4) (b) (4)	11 Sep 2020 20:46:09

US3502125

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:49

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	Josie Marshall (b) (4)	11 Sep 2020 20:46:09

US3502125

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:49

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	Josie Marshall (b) (4)	11 Sep 2020 20:46:09

US3502125

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:49

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User entered empty.	System	11 Sep 2020 20:46:09

US3502125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:56:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:51:21

US3502125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:56:49

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:51:21

US3502125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:56:49

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)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:51:21

US3502125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:56:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 20:51:21

US3502125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:56:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '09 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:51:21

US3502125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '14:49'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:51:21

US3502125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User entered '09 Sep 2020 14:49'	System	09 Sep 2020 20:51:21

US3502125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:51:21

US3502125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User entered 'ONCE'	System	09 Sep 2020 20:51:21

US3502125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:56:49

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 20:51:21

US3502125

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Josie Marshall (b) (4)	11 Sep 2020 20:47:13

US3502125

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '9 Sep 2020'	Josie Marshall (b) (4)	11 Sep 2020 20:47:13

US3502125

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '14:35'	Josie Marshall (b) (4)	11 Sep 2020 20:47:13

US3502125

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User entered '9 Sep 2020 14:35'	System	11 Sep 2020 20:47:13

US3502125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 07:56:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '9 Sep 2020'	Josie Marshall (b) (4)	11 Sep 2020 20:47:35

US3502125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:56:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Josie Marshall (b) (4) (b) (4)	11 Sep 2020 20:47:35

US3502125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:56:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Josie Marshall (b) (4)	11 Sep 2020 20:47:35

US3502125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:56:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '14:45'	Josie Marshall (b) (4)	11 Sep 2020 20:47:35

US3502125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User entered '9 Sep 2020 14:45'	System	11 Sep 2020 20:47:35

US3502125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:56:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Josie Marshall (b) (4) (b) (4)	11 Sep 2020 20:47:35

US3502125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:56:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'No (N)'	Josie Marshall (b) (4)	11 Sep 2020 20:47:35

US3502125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:56:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	Josie Marshall (b) (4)	11 Sep 2020 20:47:35

US3502125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User entered empty.	System	11 Sep 2020 20:47:35

US3502125

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Josie Marshall (b) (4)	11 Sep 2020 20:47:40

US3502125

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 07:56:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User entered '1'	System	11 Sep 2020 20:47:40

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	09 Sep 2020 20:51:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T15:13:22', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '7fda9c84-e92a-4c23-ba21-1d6395f68c29'	System	09 Sep 2020 21:14:21
User entered 'Yes (Y)'	System	09 Sep 2020 21:14:21

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T15:14:04', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '7fda9c84-e92a-4c23-ba21-1d6395f68c29'	System	09 Sep 2020 21:14:21
User entered '97.3'	System	09 Sep 2020 21:14:21

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T15:14:09', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '7fda9c84-e92a-4c23-ba21-1d6395f68c29'	System	09 Sep 2020 21:14:21
User entered 'No (N)'	System	09 Sep 2020 21:14:21

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T15:14:20', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '7fda9c84-e92a-4c23-ba21-1d6395f68c29'	System	09 Sep 2020 21:14:21
User entered '09 Sep 2020 15:14'	System	09 Sep 2020 21:14:21

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '09 Sep 2020 15:09'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '09 Sep 2020 17:39'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	09 Sep 2020 20:51:21
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T19:45:53', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'f07d16e3-65fa-48ce-81df-5b851522778f' User entered 'Yes (Y)'	System	10 Sep 2020 01:46:15
	System	10 Sep 2020 01:46:15

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T19:45:58', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'f07d16e3-65fa-48ce-81df-5b851522778f' User entered '96.5'	System	10 Sep 2020 01:46:15
	System	10 Sep 2020 01:46:15

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T19:46:02', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'f07d16e3-65fa-48ce-81df-5b851522778f'	System	10 Sep 2020 01:46:15
User entered 'No (N)'	System	10 Sep 2020 01:46:15

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T19:46:10', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'f07d16e3-65fa-48ce-81df-5b851522778f' User entered '09 Sep 2020 19:46'	System	10 Sep 2020 01:46:15
	System	10 Sep 2020 01:46:15

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '09 Sep 2020 18:34'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	09 Sep 2020 20:51:21
User entered 'Day 2'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:56:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-10T16:56:04', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'aed17c13-f767-433b-8fbb-13d4f739d8aa'	System	10 Sep 2020 22:56:25
User entered 'Yes (Y)'	System	10 Sep 2020 22:56:25

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:56:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-10T16:56:11', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'aed17c13-f767-433b-8fbb-13d4f739d8aa' User entered '97.2'	System	10 Sep 2020 22:56:25
	System	10 Sep 2020 22:56:25

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-10T16:56:15', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'aed17c13-f767-433b-8fbb-13d4f739d8aa'	System	10 Sep 2020 22:56:25
User entered 'No (N)'	System	10 Sep 2020 22:56:25

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-10T16:56:21', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'aed17c13-f767-433b-8fbb-13d4f739d8aa'	System	10 Sep 2020 22:56:25
User entered '10 Sep 2020 16:56'	System	10 Sep 2020 22:56:25

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	09 Sep 2020 20:51:21
User entered 'Day 3'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:56:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-11T22:14:54', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'b21958da-61d0-4747-a32b-2aa56d462da6' User entered 'Yes (Y)'	System	12 Sep 2020 04:15:10
	System	12 Sep 2020 04:15:10

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:56:49

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-11T22:14:59', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'b21958da-61d0-4747-a32b-2aa56d462da6' User entered '96.8'	System	12 Sep 2020 04:15:10
	System	12 Sep 2020 04:15:10

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-11T22:15:01', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'b21958da-61d0-4747-a32b-2aa56d462da6' User entered 'No (N)'	System	12 Sep 2020 04:15:10
	System	12 Sep 2020 04:15:10

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-11T22:15:06', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'b21958da-61d0-4747-a32b-2aa56d462da6'	System	12 Sep 2020 04:15:10
User entered '11 Sep 2020 22:15'	System	12 Sep 2020 04:15:10

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	09 Sep 2020 20:51:21
User entered 'Day 4'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:56:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:56:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:56:49

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:56:49

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	09 Sep 2020 20:51:21
User entered 'Day 5'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:56:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-13T20:47:42', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'd1470d58-4f96-4619-a676-c00e9f270fd6'	System	14 Sep 2020 02:47:53
User entered 'Yes (Y)'	System	14 Sep 2020 02:47:53

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:56:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-13T20:47:46', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'd1470d58-4f96-4619-a676-c00e9f270fd6' User entered '96.8'	System	14 Sep 2020 02:47:53
	System	14 Sep 2020 02:47:53

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-13T20:47:48', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'd1470d58-4f96-4619-a676-c00e9f270fd6'	System	14 Sep 2020 02:47:53
User entered 'No (N)'	System	14 Sep 2020 02:47:53

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-13T20:47:51', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'd1470d58-4f96-4619-a676-c00e9f270fd6' User entered '13 Sep 2020 20:47'	System	14 Sep 2020 02:47:53
	System	14 Sep 2020 02:47:53

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	09 Sep 2020 20:51:21
User entered 'Day 6'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:56:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-15T11:32:27', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'd2e8af2d-e81a-48b2-ae12-2256e6067f5d' User entered 'Yes (Y)'	System	15 Sep 2020 17:32:40
	System	15 Sep 2020 17:32:40

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:56:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-15T11:32:30', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'd2e8af2d-e81a-48b2-ae12-2256e6067f5d' User entered '97.7'	System	15 Sep 2020 17:32:40
	System	15 Sep 2020 17:32:40

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-15T11:32:33', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'd2e8af2d-e81a-48b2-ae12-2256e6067f5d'	System	15 Sep 2020 17:32:40
User entered 'No (N)'	System	15 Sep 2020 17:32:40

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-15T11:32:36', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'd2e8af2d-e81a-48b2-ae12-2256e6067f5d' User entered '15 Sep 2020 11:32'	System	15 Sep 2020 17:32:40
	System	15 Sep 2020 17:32:40

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	09 Sep 2020 20:51:21
User entered 'Day 7'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:56:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-15T21:38:09', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'a564db84-932b-4ee4-8e0a-d13c96dde9f3'	System	16 Sep 2020 03:38:26
User entered 'Yes (Y)'	System	16 Sep 2020 03:38:26

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:56:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-15T21:38:14', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'a564db84-932b-4ee4-8e0a-d13c96dde9f3' User entered '96.5'	System	16 Sep 2020 03:38:26
	System	16 Sep 2020 03:38:26

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-15T21:38:18', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'a564db84-932b-4ee4-8e0a-d13c96dde9f3'	System	16 Sep 2020 03:38:26
User entered 'No (N)'	System	16 Sep 2020 03:38:26

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-15T21:38:24', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'a564db84-932b-4ee4-8e0a-d13c96dde9f3'	System	16 Sep 2020 03:38:26
User entered '15 Sep 2020 21:38'	System	16 Sep 2020 03:38:26

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	09 Sep 2020 20:51:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T15:14:30', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '5beaa9d9-27ac-4aeb-8fdf-22fec7944d62'	System	09 Sep 2020 21:14:58
User entered 'None (1)'	System	09 Sep 2020 21:14:58

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T15:14:39', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '5beaa9d9-27ac-4aeb-8fdf-22fec7944d62'	System	09 Sep 2020 21:14:58
User entered 'No (N)'	System	09 Sep 2020 21:14:58

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T15:14:44', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '5beaa9d9-27ac-4aeb-8fdf-22fec7944d62'	System	09 Sep 2020 21:14:58
User entered 'No (N)'	System	09 Sep 2020 21:14:58

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T15:14:50', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '5beaa9d9-27ac-4aeb-8fdf-22fec7944d62'	System	09 Sep 2020 21:14:58
User entered 'None (1)'	System	09 Sep 2020 21:14:58

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T15:14:55', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '5beaa9d9-27ac-4aeb-8fdf-22fec7944d62'	System	09 Sep 2020 21:14:58
User entered '09 Sep 2020 15:14'	System	09 Sep 2020 21:14:58

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '09 Sep 2020 15:09'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '09 Sep 2020 17:39'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	09 Sep 2020 20:51:21
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T19:46:19', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'f76d2afa-5a0f-4bf7-8b1b-bff68582e0c8'	System	10 Sep 2020 01:46:41
User entered 'None (1)'	System	10 Sep 2020 01:46:41

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T19:46:26', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'f76d2afa-5a0f-4bf7-8b1b-bff68582e0c8'	System	10 Sep 2020 01:46:41
User entered 'No (N)'	System	10 Sep 2020 01:46:41

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T19:46:29', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'f76d2afa-5a0f-4bf7-8b1b-bff68582e0c8'	System	10 Sep 2020 01:46:41
User entered 'No (N)'	System	10 Sep 2020 01:46:41

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T19:46:33', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'f76d2afa-5a0f-4bf7-8b1b-bff68582e0c8'	System	10 Sep 2020 01:46:41
User entered 'None (1)'	System	10 Sep 2020 01:46:41

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T19:46:37', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'f76d2afa-5a0f-4bf7-8b1b-bff68582e0c8'	System	10 Sep 2020 01:46:41
User entered '09 Sep 2020 19:46'	System	10 Sep 2020 01:46:41

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '09 Sep 2020 18:34'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	09 Sep 2020 20:51:21
User entered 'Day 2'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-10T18:45:02', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'c6144d22-7322-4449-ad74-e45df0fff711'	System	11 Sep 2020 00:47:50
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 00:47:50

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-10T18:46:07', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'c6144d22-7322-4449-ad74-e45df0fff711'	System	11 Sep 2020 00:47:50
User entered 'No (N)'	System	11 Sep 2020 00:47:50

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-10T18:46:09', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'c6144d22-7322-4449-ad74-e45df0fff711'	System	11 Sep 2020 00:47:50
User entered 'Yes (Y)'	System	11 Sep 2020 00:47:50

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:56:49

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-10T18:47:32', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'c6144d22-7322-4449-ad74-e45df0fff711'	System	11 Sep 2020 00:47:50
User entered '60'	System	11 Sep 2020 00:47:50

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-10T18:47:37', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'c6144d22-7322-4449-ad74-e45df0fff711'	System	11 Sep 2020 00:47:50
User entered 'None (1)'	System	11 Sep 2020 00:47:50

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-10T18:47:48', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'c6144d22-7322-4449-ad74-e45df0fff711'	System	11 Sep 2020 00:47:50
User entered '10 Sep 2020 18:47'	System	11 Sep 2020 00:47:50

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	09 Sep 2020 20:51:21
User entered 'Day 3'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-11T22:15:15', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '170bd853-23a2-4c07-b3cd-70ec08bc1e1f' User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 04:21:45
	System	12 Sep 2020 04:21:45

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-11T22:15:22', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '170bd853-23a2-4c07-b3cd-70ec08bc1e1f' User entered 'No (N)'	System	12 Sep 2020 04:21:45
	System	12 Sep 2020 04:21:45

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-11T22:15:34', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '170bd853-23a2-4c07-b3cd-70ec08bc1e1f' User entered 'Yes (Y)'	System	12 Sep 2020 04:21:45
	System	12 Sep 2020 04:21:45

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:56:49

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-11T22:21:29', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '170bd853-23a2-4c07-b3cd-70ec08bc1e1f' User entered '50'	System	12 Sep 2020 04:21:45
	System	12 Sep 2020 04:21:45

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-11T22:21:40', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '170bd853-23a2-4c07-b3cd-70ec08bc1e1f'	System	12 Sep 2020 04:21:45
User entered 'None (1)'	System	12 Sep 2020 04:21:45

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-11T22:21:43', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '170bd853-23a2-4c07-b3cd-70ec08bc1e1f' User entered '11 Sep 2020 22:21'	System	12 Sep 2020 04:21:45
	System	12 Sep 2020 04:21:45

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	09 Sep 2020 20:51:21
User entered 'Day 4'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:56:49

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:56:49

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	09 Sep 2020 20:51:21
User entered 'Day 5'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-13T20:47:58', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '49ee728a-0072-4d02-acd8-88205e300baf' User entered 'None (1)'	System	14 Sep 2020 02:48:09
	System	14 Sep 2020 02:48:09

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-13T20:48:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '49ee728a-0072-4d02-acd8-88205e300baf' User entered 'No (N)'	System	14 Sep 2020 02:48:09
	System	14 Sep 2020 02:48:09

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-13T20:48:02', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '49ee728a-0072-4d02-acd8-88205e300baf' User entered 'No (N)'	System	14 Sep 2020 02:48:09
	System	14 Sep 2020 02:48:09

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-13T20:48:05', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '49ee728a-0072-4d02-acd8-88205e300baf' User entered 'None (1)'	System	14 Sep 2020 02:48:09
	System	14 Sep 2020 02:48:09

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-13T20:48:07', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '49ee728a-0072-4d02-acd8-88205e300baf' User entered '13 Sep 2020 20:48'	System	14 Sep 2020 02:48:09
	System	14 Sep 2020 02:48:09

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	09 Sep 2020 20:51:21
User entered 'Day 6'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-15T11:32:41', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'cf6f2d68-92fb-4b93-9b50-c7249cfde90d'	System	15 Sep 2020 17:32:54
User entered 'None (1)'	System	15 Sep 2020 17:32:54

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-15T11:32:44', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'cf6f2d68-92fb-4b93-9b50-c7249cfde90d'	System	15 Sep 2020 17:32:54
User entered 'No (N)'	System	15 Sep 2020 17:32:54

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-15T11:32:46', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'cf6f2d68-92fb-4b93-9b50-c7249cfde90d'	System	15 Sep 2020 17:32:54
User entered 'No (N)'	System	15 Sep 2020 17:32:54

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-15T11:32:48', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'cf6f2d68-92fb-4b93-9b50-c7249cfde90d'	System	15 Sep 2020 17:32:54
User entered 'None (1)'	System	15 Sep 2020 17:32:54

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-15T11:32:50', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'cf6f2d68-92fb-4b93-9b50-c7249cfde90d' User entered '15 Sep 2020 11:32'	System	15 Sep 2020 17:32:54
	System	15 Sep 2020 17:32:54

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	09 Sep 2020 20:51:21
User entered 'Day 7'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-15T21:38:27', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'd58954e7-cbc5-48d2-8b0a-d65ccb67b67a' User entered 'None (1)'	System	16 Sep 2020 03:38:38
	System	16 Sep 2020 03:38:38

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-15T21:38:29', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'd58954e7-cbc5-48d2-8b0a-d65ccb67b67a' User entered 'No (N)'	System	16 Sep 2020 03:38:38
	System	16 Sep 2020 03:38:38

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-15T21:38:31', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'd58954e7-cbc5-48d2-8b0a-d65ccb67b67a' User entered 'No (N)'	System	16 Sep 2020 03:38:38
	System	16 Sep 2020 03:38:38

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-15T21:38:32', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'd58954e7-cbc5-48d2-8b0a-d65ccb67b67a' User entered 'None (1)'	System	16 Sep 2020 03:38:38
	System	16 Sep 2020 03:38:38

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-15T21:38:34', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'd58954e7-cbc5-48d2-8b0a-d65ccb67b67a' User entered '15 Sep 2020 21:38'	System	16 Sep 2020 03:38:38
	System	16 Sep 2020 03:38:38

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	09 Sep 2020 20:51:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T15:15:12', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '5832b22b-5244-4beb-98a9-963625f0e7b3'	System	09 Sep 2020 21:15:48
User entered 'None (0)'	System	09 Sep 2020 21:15:48

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T15:15:18', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '5832b22b-5244-4beb-98a9-963625f0e7b3'	System	09 Sep 2020 21:15:48
User entered 'None (0)'	System	09 Sep 2020 21:15:48

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T15:15:22', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '5832b22b-5244-4beb-98a9-963625f0e7b3'	System	09 Sep 2020 21:15:48
User entered 'None (0)'	System	09 Sep 2020 21:15:48

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T15:15:25', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '5832b22b-5244-4beb-98a9-963625f0e7b3'	System	09 Sep 2020 21:15:48
User entered 'None (0)'	System	09 Sep 2020 21:15:48

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T15:15:28', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '5832b22b-5244-4beb-98a9-963625f0e7b3'	System	09 Sep 2020 21:15:48
User entered 'None (0)'	System	09 Sep 2020 21:15:48

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T15:15:32', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '5832b22b-5244-4beb-98a9-963625f0e7b3'	System	09 Sep 2020 21:15:48
User entered 'None (0)'	System	09 Sep 2020 21:15:48

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T15:15:38', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '5832b22b-5244-4beb-98a9-963625f0e7b3'	System	09 Sep 2020 21:15:48
User entered 'No (N)'	System	09 Sep 2020 21:15:48

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T15:15:45', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '5832b22b-5244-4beb-98a9-963625f0e7b3'	System	09 Sep 2020 21:15:48
User entered '09 Sep 2020 15:15'	System	09 Sep 2020 21:15:48

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '09 Sep 2020 15:09'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '09 Sep 2020 17:39'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	09 Sep 2020 20:51:21
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T19:46:42', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '05d5ee15-bc30-4a4e-836e-dc84002b4c6e' User entered 'None (0)'	System	10 Sep 2020 01:47:09
	System	10 Sep 2020 01:47:09

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T19:46:46', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '05d5ee15-bc30-4a4e-836e-dc84002b4c6e' User entered 'None (0)'	System	10 Sep 2020 01:47:09
	System	10 Sep 2020 01:47:09

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T19:46:48', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '05d5ee15-bc30-4a4e-836e-dc84002b4c6e' User entered 'None (0)'	System	10 Sep 2020 01:47:09
	System	10 Sep 2020 01:47:09

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T19:46:52', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '05d5ee15-bc30-4a4e-836e-dc84002b4c6e' User entered 'None (0)'	System	10 Sep 2020 01:47:09
	System	10 Sep 2020 01:47:09

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T19:46:55', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '05d5ee15-bc30-4a4e-836e-dc84002b4c6e' User entered 'None (0)'	System	10 Sep 2020 01:47:09
	System	10 Sep 2020 01:47:09

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T19:46:57', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '05d5ee15-bc30-4a4e-836e-dc84002b4c6e' User entered 'None (0)'	System	10 Sep 2020 01:47:09
	System	10 Sep 2020 01:47:09

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T19:47:03', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '05d5ee15-bc30-4a4e-836e-dc84002b4c6e' User entered 'No (N)'	System	10 Sep 2020 01:47:09
	System	10 Sep 2020 01:47:09

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-09T19:47:06', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '05d5ee15-bc30-4a4e-836e-dc84002b4c6e' User entered '09 Sep 2020 19:47'	System	10 Sep 2020 01:47:09
	System	10 Sep 2020 01:47:09

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '09 Sep 2020 18:34'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	09 Sep 2020 20:51:21
User entered 'Day 2'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:56:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-10T18:47:54', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'a800c07a-d362-4d06-9048-78f55bd95a1d' User entered 'None (0)'	System	11 Sep 2020 00:50:59
	System	11 Sep 2020 00:50:59

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:56:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-10T18:48:13', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'a800c07a-d362-4d06-9048-78f55bd95a1d' User entered 'None (0)'	System	11 Sep 2020 00:50:59
	System	11 Sep 2020 00:50:59

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:56:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-10T18:50:21', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'a800c07a-d362-4d06-9048-78f55bd95a1d' User entered 'None (0)'	System	11 Sep 2020 00:50:59
	System	11 Sep 2020 00:50:59

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:56:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-10T18:50:27', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'a800c07a-d362-4d06-9048-78f55bd95a1d' User entered 'None (0)'	System	11 Sep 2020 00:50:59
	System	11 Sep 2020 00:50:59

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:56:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-10T18:50:29', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'a800c07a-d362-4d06-9048-78f55bd95a1d' User entered 'None (0)'	System	11 Sep 2020 00:50:59
	System	11 Sep 2020 00:50:59

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:56:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-10T18:50:37', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'a800c07a-d362-4d06-9048-78f55bd95a1d'	System	11 Sep 2020 00:50:59
User entered 'No interference with activity (1)'	System	11 Sep 2020 00:50:59

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-10T18:50:47', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'a800c07a-d362-4d06-9048-78f55bd95a1d' User entered 'No (N)'	System	11 Sep 2020 00:50:59
	System	11 Sep 2020 00:50:59

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:56:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-10T18:50:56', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'a800c07a-d362-4d06-9048-78f55bd95a1d' User entered '10 Sep 2020 18:50'	System	11 Sep 2020 00:50:59
	System	11 Sep 2020 00:50:59

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	09 Sep 2020 20:51:21
User entered 'Day 3'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:56:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-11T22:21:49', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '38536e97-a615-498c-b7bf-9979eb20a258' User entered 'None (0)'	System	12 Sep 2020 04:22:40
	System	12 Sep 2020 04:22:40

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:56:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-11T22:21:54', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '38536e97-a615-498c-b7bf-9979eb20a258' User entered 'None (0)'	System	12 Sep 2020 04:22:40
	System	12 Sep 2020 04:22:40

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:56:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-11T22:22:06', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '38536e97-a615-498c-b7bf-9979eb20a258'	System	12 Sep 2020 04:22:40
User entered 'No interference with activity (1)'	System	12 Sep 2020 04:22:40

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:56:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-11T22:22:19', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '38536e97-a615-498c-b7bf-9979eb20a258' User entered 'None (0)'	System	12 Sep 2020 04:22:40
	System	12 Sep 2020 04:22:40

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:56:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-11T22:22:22', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '38536e97-a615-498c-b7bf-9979eb20a258' User entered 'None (0)'	System	12 Sep 2020 04:22:40
	System	12 Sep 2020 04:22:40

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:56:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-11T22:22:31', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '38536e97-a615-498c-b7bf-9979eb20a258'	System	12 Sep 2020 04:22:40
User entered 'No interference with activity (1)'	System	12 Sep 2020 04:22:40

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-11T22:22:36', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '38536e97-a615-498c-b7bf-9979eb20a258'	System	12 Sep 2020 04:22:40
User entered 'No (N)'	System	12 Sep 2020 04:22:40

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:56:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-11T22:22:38', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '38536e97-a615-498c-b7bf-9979eb20a258' User entered '11 Sep 2020 22:22'	System	12 Sep 2020 04:22:40
	System	12 Sep 2020 04:22:40

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	09 Sep 2020 20:51:21
User entered 'Day 4'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:56:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:56:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:56:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:56:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:56:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:56:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:56:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	09 Sep 2020 20:51:21
User entered 'Day 5'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:56:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-13T20:48:12', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'e9e67cad-5e2d-43c5-90ca-575570e8c8d8' User entered 'None (0)'	System	14 Sep 2020 02:48:33
	System	14 Sep 2020 02:48:33

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:56:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-13T20:48:14', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'e9e67cad-5e2d-43c5-90ca-575570e8c8d8'	System	14 Sep 2020 02:48:33
User entered 'None (0)'	System	14 Sep 2020 02:48:33

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:56:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-13T20:48:16', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'e9e67cad-5e2d-43c5-90ca-575570e8c8d8'	System	14 Sep 2020 02:48:33
User entered 'None (0)'	System	14 Sep 2020 02:48:33

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:56:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-13T20:48:18', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'e9e67cad-5e2d-43c5-90ca-575570e8c8d8' User entered 'None (0)'	System	14 Sep 2020 02:48:33
	System	14 Sep 2020 02:48:33

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:56:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-13T20:48:20', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'e9e67cad-5e2d-43c5-90ca-575570e8c8d8' User entered 'None (0)'	System	14 Sep 2020 02:48:33
	System	14 Sep 2020 02:48:33

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:56:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-13T20:48:22', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'e9e67cad-5e2d-43c5-90ca-575570e8c8d8' User entered 'None (0)'	System	14 Sep 2020 02:48:33
	System	14 Sep 2020 02:48:33

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-13T20:48:27', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'e9e67cad-5e2d-43c5-90ca-575570e8c8d8' User entered 'No (N)'	System	14 Sep 2020 02:48:33
	System	14 Sep 2020 02:48:33

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:56:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-13T20:48:29', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'e9e67cad-5e2d-43c5-90ca-575570e8c8d8'	System	14 Sep 2020 02:48:33
User entered '13 Sep 2020 20:48'	System	14 Sep 2020 02:48:33

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	09 Sep 2020 20:51:21
User entered 'Day 6'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:56:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-15T11:32:55', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'e93d55e3-efcc-4048-b2af-e449854be651' User entered 'None (0)'	System	15 Sep 2020 17:33:14
	System	15 Sep 2020 17:33:14

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:56:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-15T11:32:58', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'e93d55e3-efcc-4048-b2af-e449854be651'	System	15 Sep 2020 17:33:14
User entered 'None (0)'	System	15 Sep 2020 17:33:14

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:56:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-15T11:33:01', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'e93d55e3-efcc-4048-b2af-e449854be651' User entered 'None (0)'	System	15 Sep 2020 17:33:14
	System	15 Sep 2020 17:33:14

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:56:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-15T11:33:03', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'e93d55e3-efcc-4048-b2af-e449854be651' User entered 'None (0)'	System	15 Sep 2020 17:33:14
	System	15 Sep 2020 17:33:14

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:56:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-15T11:33:04', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'e93d55e3-efcc-4048-b2af-e449854be651' User entered 'None (0)'	System	15 Sep 2020 17:33:14
	System	15 Sep 2020 17:33:14

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:56:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-15T11:33:06', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'e93d55e3-efcc-4048-b2af-e449854be651' User entered 'None (0)'	System	15 Sep 2020 17:33:14
	System	15 Sep 2020 17:33:14

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-15T11:33:09', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'e93d55e3-efcc-4048-b2af-e449854be651'	System	15 Sep 2020 17:33:14
User entered 'No (N)'	System	15 Sep 2020 17:33:14

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:56:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-09-15T11:33:12', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'e93d55e3-efcc-4048-b2af-e449854be651'	System	15 Sep 2020 17:33:14
User entered '15 Sep 2020 11:33'	System	15 Sep 2020 17:33:14

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	09 Sep 2020 20:51:21
User entered 'Day 7'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:56:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:56:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:56:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:56:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:56:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:56:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:56:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 20:51:21

US3502125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 20:51:21

US3502125

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	17 Sep 2020 23:46:49

US3502125

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '16 Sep 2020'	Suzanne Fiorillo (b) (4)	17 Sep 2020 23:46:49

US3502125

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Contact Made (CONTACT MADE)'	Suzanne Fiorillo (b) (4)	17 Sep 2020 23:46:49

US3502125

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	Suzanne Fiorillo (b) (4)	17 Sep 2020 23:46:49

US3502125

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	17 Sep 2020 23:46:53

US3502125

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User entered '1'	System	17 Sep 2020 23:46:53

US3502125

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Laurel Ware (b) (4)	30 Sep 2020 17:40:40

US3502125

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '26 Sep 2020'	(b) (4) Laurel Ware (b) (4) (b) (4)	30 Sep 2020 17:40:40

US3502125

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Contact Made (CONTACT MADE)'	Laurel Ware (b) (4)	30 Sep 2020 17:40:40

US3502125

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	(b) (4) Laurel Ware (b) (4)	30 Sep 2020 17:40:40
	(b) (4)	

US3502125

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Laurel Ware (b) (4)	30 Sep 2020 17:40:26

US3502125

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User entered '1'	System	30 Sep 2020 17:40:26

US3502125

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Laurel Ware (b) (4)	02 Oct 2020 20:02:00

US3502125

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '01 Oct 2020'	Laurel Ware (b) (4)	02 Oct 2020 20:02:00

US3502125

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Contact Made (CONTACT MADE)'	Laurel Ware (b) (4)	02 Oct 2020 20:02:00

US3502125

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	(b) (4) Laurel Ware (b) (4)	02 Oct 2020 20:02:00
	(b) (4)	

US3502125

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Laurel Ware (b) (4)	02 Oct 2020 20:02:09

US3502125

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User entered '1'	System	02 Oct 2020 20:02:09

US3502125

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:56:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:16:39

US3502125

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:16:39

US3502125

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:16:39

US3502125

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:56:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered 'VISIT2'	System	07 Oct 2020 20:16:39

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '13:55'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered '07 Oct 2020 13:55'	System	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered 'Forehead'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '68'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered 'bpm'	System	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '12'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered 'breaths/min'	System	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '132'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered 'mmHg'	System	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '74'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered 'mmHg'	System	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '15:08'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered '07 Oct 2020 15:08'	System	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered 'Forehead'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '64'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered 'bpm'	System	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '14'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered 'breaths/min'	System	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '115'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered 'mmHg'	System	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '80'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered 'mmHg'	System	07 Oct 2020 22:34:44

US3502125

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:56:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:34:53

US3502125

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:56:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:34:53

US3502125

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:49

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:35:14

US3502125

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:49

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:35:14

US3502125

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:49

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:35:14

US3502125

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:49

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:35:14

US3502125

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:49

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:35:14

US3502125

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:49

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:35:14

US3502125

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:49

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:35:14

US3502125

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:49

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered empty.	System	07 Oct 2020 22:35:14

US3502125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:39:09

US3502125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:39:09

US3502125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:49

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)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:39:09

US3502125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered 'MRNA-1273 OR PLACEBO'	System	07 Oct 2020 20:39:09

US3502125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:39:09

US3502125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '14:37'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:39:09

US3502125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered '07 Oct 2020 14:37'	System	07 Oct 2020 20:39:09

US3502125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:39:09

US3502125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered 'ONCE'	System	07 Oct 2020 20:39:09

US3502125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:49

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered 'INTRAMUSCULAR'	System	07 Oct 2020 20:39:09

US3502125

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:35:35

US3502125

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:35:35

US3502125

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '14:30'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:35:35

US3502125

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered '07 Oct 2020 14:30'	System	07 Oct 2020 22:35:35

US3502125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 07:56:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:35:48

US3502125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:56:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	07 Oct 2020 22:35:48

US3502125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:56:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:35:48

US3502125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:56:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '14:33'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:35:48

US3502125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered '07 Oct 2020 14:33'	System	07 Oct 2020 22:35:48

US3502125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:56:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	07 Oct 2020 22:35:48

US3502125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:56:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:35:48

US3502125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:56:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:35:48

US3502125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered empty.	System	07 Oct 2020 22:35:48

US3502125

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 22:35:53

US3502125

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered '1'	System	07 Oct 2020 22:35:53

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	07 Oct 2020 20:39:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T15:00:56', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '48404bda-d06a-4030-afa6-4a477212ebe7' User entered 'Yes (Y)'	System	07 Oct 2020 21:01:24
	System	07 Oct 2020 21:01:24

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T15:01:04', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '48404bda-d06a-4030-afa6-4a477212ebe7' User entered '97.3'	System	07 Oct 2020 21:01:24
	System	07 Oct 2020 21:01:24

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T15:01:09', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '48404bda-d06a-4030-afa6-4a477212ebe7'	System	07 Oct 2020 21:01:24
User entered 'No (N)'	System	07 Oct 2020 21:01:24

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T15:01:20', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '48404bda-d06a-4030-afa6-4a477212ebe7' User entered '07 Oct 2020 15:01'	System	07 Oct 2020 21:01:24
	System	07 Oct 2020 21:01:24

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '07 Oct 2020 14:57'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '07 Oct 2020 17:27'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	07 Oct 2020 20:39:09
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T19:25:06', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '1390d3bd-6bc9-4409-94b8-b517549da3a7'	System	08 Oct 2020 01:25:23
User entered 'Yes (Y)'	System	08 Oct 2020 01:25:23

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T19:25:11', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '1390d3bd-6bc9-4409-94b8-b517549da3a7'	System	08 Oct 2020 01:25:23
User entered '97.9'	System	08 Oct 2020 01:25:23

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T19:25:14', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '1390d3bd-6bc9-4409-94b8-b517549da3a7'	System	08 Oct 2020 01:25:23
User entered 'No (N)'	System	08 Oct 2020 01:25:23

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T19:25:20', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '1390d3bd-6bc9-4409-94b8-b517549da3a7'	System	08 Oct 2020 01:25:23
User entered '07 Oct 2020 19:25'	System	08 Oct 2020 01:25:23

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '07 Oct 2020 18:22'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	07 Oct 2020 20:39:09
User entered 'Day 2'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:56:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-08T15:11:36', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '339c05b6-9d10-4cc2-9e05-9aa03046eb49' User entered 'Yes (Y)'	System	08 Oct 2020 21:11:57
	System	08 Oct 2020 21:11:57

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:56:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-08T15:11:41', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '339c05b6-9d10-4cc2-9e05-9aa03046eb49' User entered '99.3'	System	08 Oct 2020 21:11:57
	System	08 Oct 2020 21:11:57

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-08T15:11:45', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '339c05b6-9d10-4cc2-9e05-9aa03046eb49' User entered 'Yes (Y)'	System	08 Oct 2020 21:11:57
	System	08 Oct 2020 21:11:57

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:56:49

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Will confirm in safety call' (Site from System).	(b) (4), (b) (6)	16 Oct 2020 03:40:53
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Patrishia Adkins (b) (4)	14 Oct 2020 22:19:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-08T15:11:51', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '339c05b6-9d10-4cc2-9e05-9aa03046eb49'	(b) (4)	
User entered '1'	System	08 Oct 2020 21:11:57
	System	08 Oct 2020 21:11:57
	System	08 Oct 2020 21:11:57

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:56:49

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-08T15:11:51', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '339c05b6-9d10-4cc2-9e05-9aa03046eb49' User entered '0'	System	08 Oct 2020 21:11:57
	System	08 Oct 2020 21:11:57

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-08T15:11:55', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '339c05b6-9d10-4cc2-9e05-9aa03046eb49' User entered '08 Oct 2020 15:11'	System	08 Oct 2020 21:11:57
	System	08 Oct 2020 21:11:57

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	07 Oct 2020 20:39:09
User entered 'Day 3'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:56:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-09T18:08:43', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '263983f1-b703-498f-b850-dd8fb989557e' User entered 'Yes (Y)'	System	10 Oct 2020 00:08:59
	System	10 Oct 2020 00:08:59

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:56:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-09T18:08:50', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '263983f1-b703-498f-b850-dd8fb989557e' User entered '97.9'	System	10 Oct 2020 00:08:59
	System	10 Oct 2020 00:08:59

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-09T18:08:53', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '263983f1-b703-498f-b850-dd8fb989557e' User entered 'No (N)'	System	10 Oct 2020 00:08:59
	System	10 Oct 2020 00:08:59

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-09T18:08:56', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '263983f1-b703-498f-b850-dd8fb989557e' User entered '09 Oct 2020 18:08'	System	10 Oct 2020 00:08:59
	System	10 Oct 2020 00:08:59

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	07 Oct 2020 20:39:09
User entered 'Day 4'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:56:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T04:13:49', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'fbdd994c-647e-4700-baf1-1b43506de644' User entered 'Yes (Y)'	System	11 Oct 2020 10:14:18
	System	11 Oct 2020 10:14:18

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:56:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T04:14:11', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'fbdd994c-647e-4700-baf1-1b43506de644'	System	11 Oct 2020 10:14:18
User entered '98.1'	System	11 Oct 2020 10:14:18

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T04:14:13', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'fbdd994c-647e-4700-baf1-1b43506de644'	System	11 Oct 2020 10:14:18
User entered 'No (N)'	System	11 Oct 2020 10:14:18

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T04:14:16', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'fbdd994c-647e-4700-baf1-1b43506de644'	System	11 Oct 2020 10:14:18
User entered '11 Oct 2020 04:14'	System	11 Oct 2020 10:14:18

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	07 Oct 2020 20:39:09
User entered 'Day 5'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:56:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T21:16:32', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'daf975b2-cc58-4459-a79d-36e82255c36d' User entered 'Yes (Y)'	System	12 Oct 2020 03:16:48
	System	12 Oct 2020 03:16:48

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:56:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T21:16:36', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'daf975b2-cc58-4459-a79d-36e82255c36d' User entered '97.5'	System	12 Oct 2020 03:16:48
	System	12 Oct 2020 03:16:48

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T21:16:45', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'daf975b2-cc58-4459-a79d-36e82255c36d' User entered 'No (N)'	System	12 Oct 2020 03:16:48
	System	12 Oct 2020 03:16:48

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T21:16:47', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'daf975b2-cc58-4459-a79d-36e82255c36d' User entered '11 Oct 2020 21:16'	System	12 Oct 2020 03:16:48
	System	12 Oct 2020 03:16:48

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	07 Oct 2020 20:39:09
User entered 'Day 6'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:56:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-12T17:15:02', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'cdef712e-fd43-4bd9-8e1f-18274bc5a63d' User entered 'Yes (Y)'	System	12 Oct 2020 23:15:15
	System	12 Oct 2020 23:15:15

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:56:49

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-12T17:15:08', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'cdef712e-fd43-4bd9-8e1f-18274bc5a63d' User entered '97.9'	System	12 Oct 2020 23:15:15
	System	12 Oct 2020 23:15:15

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-12T17:15:11', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'cdef712e-fd43-4bd9-8e1f-18274bc5a63d'	System	12 Oct 2020 23:15:15
User entered 'No (N)'	System	12 Oct 2020 23:15:15

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-12T17:15:14', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'cdef712e-fd43-4bd9-8e1f-18274bc5a63d' User entered '12 Oct 2020 17:15'	System	12 Oct 2020 23:15:15
	System	12 Oct 2020 23:15:15

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	07 Oct 2020 20:39:09
User entered 'Day 7'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:56:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-13T21:25:57', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '9d5678d6-2192-48da-a5a0-df12873490b4' User entered 'Yes (Y)'	System	14 Oct 2020 03:26:11
	System	14 Oct 2020 03:26:11

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:56:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-13T21:26:01', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '9d5678d6-2192-48da-a5a0-df12873490b4' User entered '97.5'	System	14 Oct 2020 03:26:11
	System	14 Oct 2020 03:26:11

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-13T21:26:04', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '9d5678d6-2192-48da-a5a0-df12873490b4' User entered 'No (N)'	System	14 Oct 2020 03:26:11
	System	14 Oct 2020 03:26:11

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-13T21:26:06', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '9d5678d6-2192-48da-a5a0-df12873490b4' User entered '13 Oct 2020 21:26'	System	14 Oct 2020 03:26:11
	System	14 Oct 2020 03:26:11

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	07 Oct 2020 20:39:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T15:01:35', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '293e3c2b-e6ba-48cd-bdcf-81033d178f11'	System	07 Oct 2020 21:02:03
User entered 'None (1)'	System	07 Oct 2020 21:02:03

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T15:01:42', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '293e3c2b-e6ba-48cd-bdcf-81033d178f11'	System	07 Oct 2020 21:02:03
User entered 'No (N)'	System	07 Oct 2020 21:02:03

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T15:01:48', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '293e3c2b-e6ba-48cd-bdcf-81033d178f11'	System	07 Oct 2020 21:02:03
User entered 'No (N)'	System	07 Oct 2020 21:02:03

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T15:01:55', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '293e3c2b-e6ba-48cd-bdcf-81033d178f11'	System	07 Oct 2020 21:02:03
User entered 'None (1)'	System	07 Oct 2020 21:02:03

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T15:01:58', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '293e3c2b-e6ba-48cd-bdcf-81033d178f11' User entered '07 Oct 2020 15:01'	System	07 Oct 2020 21:02:03
	System	07 Oct 2020 21:02:03

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '07 Oct 2020 14:57'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '07 Oct 2020 17:27'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	07 Oct 2020 20:39:09
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T19:25:28', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'ecdbe6f1-0562-4c20-91d8-47eb465a9148'	System	08 Oct 2020 01:26:00
User entered 'Does not interfere with activity (2)'	System	08 Oct 2020 01:26:00

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T19:25:32', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'ecdbe6f1-0562-4c20-91d8-47eb465a9148'	System	08 Oct 2020 01:26:00
User entered 'No (N)'	System	08 Oct 2020 01:26:00

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T19:25:50', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'ecdbe6f1-0562-4c20-91d8-47eb465a9148' User entered 'No (N)'	System	08 Oct 2020 01:26:00
	System	08 Oct 2020 01:26:00

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T19:25:53', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'ecdbe6f1-0562-4c20-91d8-47eb465a9148'	System	08 Oct 2020 01:26:00
User entered 'None (1)'	System	08 Oct 2020 01:26:00

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T19:25:57', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'ecdbe6f1-0562-4c20-91d8-47eb465a9148' User entered '07 Oct 2020 19:25'	System	08 Oct 2020 01:26:00
	System	08 Oct 2020 01:26:00

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '07 Oct 2020 18:22'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	07 Oct 2020 20:39:09
User entered 'Day 2'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-08T15:12:11', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'ed9e5fee-8f9f-4121-b9c1-72b388eee708'	System	08 Oct 2020 21:12:56
User entered 'Does not interfere with activity (2)'	System	08 Oct 2020 21:12:56

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-08T15:12:14', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'ed9e5fee-8f9f-4121-b9c1-72b388eee708'	System	08 Oct 2020 21:12:56
User entered 'No (N)'	System	08 Oct 2020 21:12:56

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-08T15:12:46', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'ed9e5fee-8f9f-4121-b9c1-72b388eee708'	System	08 Oct 2020 21:12:56
User entered 'No (N)'	System	08 Oct 2020 21:12:56

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-08T15:12:51', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'ed9e5fee-8f9f-4121-b9c1-72b388eee708'	System	08 Oct 2020 21:12:56
User entered 'None (1)'	System	08 Oct 2020 21:12:56

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-08T15:12:54', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'ed9e5fee-8f9f-4121-b9c1-72b388eee708' User entered '08 Oct 2020 15:12'	System	08 Oct 2020 21:12:56
	System	08 Oct 2020 21:12:56

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	07 Oct 2020 20:39:09
User entered 'Day 3'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-09T18:09:11', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '6a5c3c92-1734-4ffe-ba56-da9d128d6cf5'	System	10 Oct 2020 00:09:27
User entered 'Does not interfere with activity (2)'	System	10 Oct 2020 00:09:27

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-09T18:09:14', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '6a5c3c92-1734-4ffe-ba56-da9d128d6cf5'	System	10 Oct 2020 00:09:27
User entered 'No (N)'	System	10 Oct 2020 00:09:27

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-09T18:09:20', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '6a5c3c92-1734-4ffe-ba56-da9d128d6cf5'	System	10 Oct 2020 00:09:27
User entered 'No (N)'	System	10 Oct 2020 00:09:27

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-09T18:09:23', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '6a5c3c92-1734-4ffe-ba56-da9d128d6cf5'	System	10 Oct 2020 00:09:27
User entered 'None (1)'	System	10 Oct 2020 00:09:27

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-09T18:09:25', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '6a5c3c92-1734-4ffe-ba56-da9d128d6cf5' User entered '09 Oct 2020 18:09'	System	10 Oct 2020 00:09:27
	System	10 Oct 2020 00:09:27

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	07 Oct 2020 20:39:09
User entered 'Day 4'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T04:14:21', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '47435a28-9728-4d5b-a577-4048314a0e33'	System	11 Oct 2020 10:14:35
User entered 'None (1)'	System	11 Oct 2020 10:14:35

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T04:14:24', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '47435a28-9728-4d5b-a577-4048314a0e33'	System	11 Oct 2020 10:14:35
User entered 'No (N)'	System	11 Oct 2020 10:14:35

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T04:14:26', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '47435a28-9728-4d5b-a577-4048314a0e33'	System	11 Oct 2020 10:14:35
User entered 'No (N)'	System	11 Oct 2020 10:14:35

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T04:14:29', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '47435a28-9728-4d5b-a577-4048314a0e33'	System	11 Oct 2020 10:14:35
User entered 'None (1)'	System	11 Oct 2020 10:14:35

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T04:14:32', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '47435a28-9728-4d5b-a577-4048314a0e33'	System	11 Oct 2020 10:14:35
User entered '11 Oct 2020 04:14'	System	11 Oct 2020 10:14:35

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	07 Oct 2020 20:39:09
User entered 'Day 5'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T21:16:53', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'ef0267dc-1c92-4fc0-90ef-4de76867210f'	System	12 Oct 2020 03:17:06
User entered 'None (1)'	System	12 Oct 2020 03:17:06

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T21:16:55', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'ef0267dc-1c92-4fc0-90ef-4de76867210f' User entered 'No (N)'	System	12 Oct 2020 03:17:06
	System	12 Oct 2020 03:17:06

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T21:16:58', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'ef0267dc-1c92-4fc0-90ef-4de76867210f' User entered 'No (N)'	System	12 Oct 2020 03:17:06
	System	12 Oct 2020 03:17:06

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T21:17:01', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'ef0267dc-1c92-4fc0-90ef-4de76867210f'	System	12 Oct 2020 03:17:06
User entered 'None (1)'	System	12 Oct 2020 03:17:06

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T21:17:04', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'ef0267dc-1c92-4fc0-90ef-4de76867210f' User entered '11 Oct 2020 21:17'	System	12 Oct 2020 03:17:06
	System	12 Oct 2020 03:17:06

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	07 Oct 2020 20:39:09
User entered 'Day 6'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-12T17:15:18', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '9dcec2e0-d900-4d4f-9038-1a5ebe284f71'	System	12 Oct 2020 23:15:51
User entered 'None (1)'	System	12 Oct 2020 23:15:51

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-12T17:15:21', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '9dcec2e0-d900-4d4f-9038-1a5ebe284f71'	System	12 Oct 2020 23:15:51
User entered 'No (N)'	System	12 Oct 2020 23:15:51

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-12T17:15:23', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '9dcec2e0-d900-4d4f-9038-1a5ebe284f71'	System	12 Oct 2020 23:15:51
User entered 'No (N)'	System	12 Oct 2020 23:15:51

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-12T17:15:47', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '9dcec2e0-d900-4d4f-9038-1a5ebe284f71'	System	12 Oct 2020 23:15:51
User entered 'None (1)'	System	12 Oct 2020 23:15:51

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-12T17:15:49', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '9dcec2e0-d900-4d4f-9038-1a5ebe284f71' User entered '12 Oct 2020 17:15'	System	12 Oct 2020 23:15:51
	System	12 Oct 2020 23:15:51

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	07 Oct 2020 20:39:09
User entered 'Day 7'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-13T21:26:09', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'e9191123-9c84-4758-96c7-48a6addf1527'	System	14 Oct 2020 03:26:24
User entered 'None (1)'	System	14 Oct 2020 03:26:24

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-13T21:26:11', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'e9191123-9c84-4758-96c7-48a6addf1527'	System	14 Oct 2020 03:26:24
User entered 'No (N)'	System	14 Oct 2020 03:26:24

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-13T21:26:14', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'e9191123-9c84-4758-96c7-48a6addf1527'	System	14 Oct 2020 03:26:24
User entered 'No (N)'	System	14 Oct 2020 03:26:24

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:56:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-13T21:26:16', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'e9191123-9c84-4758-96c7-48a6addf1527'	System	14 Oct 2020 03:26:24
User entered 'None (1)'	System	14 Oct 2020 03:26:24

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:56:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-13T21:26:18', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'e9191123-9c84-4758-96c7-48a6addf1527'	System	14 Oct 2020 03:26:24
User entered '13 Oct 2020 21:26'	System	14 Oct 2020 03:26:24

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	07 Oct 2020 20:39:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T15:02:02', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'dc3d0817-1da3-48c6-b1f0-41cb9077e757'	System	07 Oct 2020 21:02:26
User entered 'None (0)'	System	07 Oct 2020 21:02:26

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T15:02:08', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'dc3d0817-1da3-48c6-b1f0-41cb9077e757' User entered 'None (0)'	System	07 Oct 2020 21:02:26
	System	07 Oct 2020 21:02:26

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T15:02:13', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'dc3d0817-1da3-48c6-b1f0-41cb9077e757'	System	07 Oct 2020 21:02:26
User entered 'None (0)'	System	07 Oct 2020 21:02:26

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T15:02:16', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'dc3d0817-1da3-48c6-b1f0-41cb9077e757'	System	07 Oct 2020 21:02:26
User entered 'None (0)'	System	07 Oct 2020 21:02:26

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T15:02:18', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'dc3d0817-1da3-48c6-b1f0-41cb9077e757'	System	07 Oct 2020 21:02:26
User entered 'None (0)'	System	07 Oct 2020 21:02:26

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T15:02:20', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'dc3d0817-1da3-48c6-b1f0-41cb9077e757' User entered 'None (0)'	System	07 Oct 2020 21:02:26
	System	07 Oct 2020 21:02:26

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T15:02:22', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'dc3d0817-1da3-48c6-b1f0-41cb9077e757'	System	07 Oct 2020 21:02:26
User entered 'No (N)'	System	07 Oct 2020 21:02:26

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T15:02:25', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'dc3d0817-1da3-48c6-b1f0-41cb9077e757'	System	07 Oct 2020 21:02:26
User entered '07 Oct 2020 15:02'	System	07 Oct 2020 21:02:26

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '07 Oct 2020 14:57'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '07 Oct 2020 17:27'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	07 Oct 2020 20:39:09
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T19:26:02', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '98ae9274-2f68-4210-8ff1-bcdfa8403271' User entered 'None (0)'	System	08 Oct 2020 01:26:25
	System	08 Oct 2020 01:26:25

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T19:26:04', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '98ae9274-2f68-4210-8ff1-bcdfa8403271'	System	08 Oct 2020 01:26:25
User entered 'None (0)'	System	08 Oct 2020 01:26:25

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T19:26:08', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '98ae9274-2f68-4210-8ff1-bcdfa8403271'	System	08 Oct 2020 01:26:25
User entered 'None (0)'	System	08 Oct 2020 01:26:25

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T19:26:11', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '98ae9274-2f68-4210-8ff1-bcdfa8403271' User entered 'None (0)'	System	08 Oct 2020 01:26:25
	System	08 Oct 2020 01:26:25

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T19:26:15', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '98ae9274-2f68-4210-8ff1-bcdfa8403271' User entered 'None (0)'	System	08 Oct 2020 01:26:25
	System	08 Oct 2020 01:26:25

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T19:26:17', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '98ae9274-2f68-4210-8ff1-bcdfa8403271' User entered 'None (0)'	System	08 Oct 2020 01:26:25
	System	08 Oct 2020 01:26:25

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T19:26:22', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '98ae9274-2f68-4210-8ff1-bcdfa8403271'	System	08 Oct 2020 01:26:25
User entered 'No (N)'	System	08 Oct 2020 01:26:25

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-07T19:26:24', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '98ae9274-2f68-4210-8ff1-bcdfa8403271'	System	08 Oct 2020 01:26:25
User entered '07 Oct 2020 19:26'	System	08 Oct 2020 01:26:25

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '07 Oct 2020 18:22'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	07 Oct 2020 20:39:09
User entered 'Day 2'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:56:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-08T15:13:13', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '82d8a7c3-43cf-4de6-bad0-53f05d1069b3'	System	08 Oct 2020 21:14:10
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	08 Oct 2020 21:14:10

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:56:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-08T15:13:19', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '82d8a7c3-43cf-4de6-bad0-53f05d1069b3'	System	08 Oct 2020 21:14:10
User entered 'Some interference with activity (2)'	System	08 Oct 2020 21:14:10

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:56:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-08T15:13:27', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '82d8a7c3-43cf-4de6-bad0-53f05d1069b3'	System	08 Oct 2020 21:14:10
User entered 'Some interference with activity (2)'	System	08 Oct 2020 21:14:10

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:56:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-08T15:13:49', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '82d8a7c3-43cf-4de6-bad0-53f05d1069b3' User entered 'None (0)'	System	08 Oct 2020 21:14:10
	System	08 Oct 2020 21:14:10

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:56:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-08T15:13:54', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '82d8a7c3-43cf-4de6-bad0-53f05d1069b3' User entered 'None (0)'	System	08 Oct 2020 21:14:10
	System	08 Oct 2020 21:14:10

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:56:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-08T15:13:57', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '82d8a7c3-43cf-4de6-bad0-53f05d1069b3'	System	08 Oct 2020 21:14:10
User entered 'Some interference with activity not requiring medical attention (2)'	System	08 Oct 2020 21:14:10

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-08T15:14:04', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '82d8a7c3-43cf-4de6-bad0-53f05d1069b3' User entered 'No (N)'	System	08 Oct 2020 21:14:10
	System	08 Oct 2020 21:14:10

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:56:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-08T15:14:07', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '82d8a7c3-43cf-4de6-bad0-53f05d1069b3' User entered '08 Oct 2020 15:14'	System	08 Oct 2020 21:14:10
	System	08 Oct 2020 21:14:10

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	07 Oct 2020 20:39:09
User entered 'Day 3'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:56:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-09T18:09:31', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '38c47bcb-84e2-400a-ac55-cf4c08912a3a' User entered 'None (0)'	System	10 Oct 2020 00:10:09
	System	10 Oct 2020 00:10:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:56:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-09T18:09:49', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '38c47bcb-84e2-400a-ac55-cf4c08912a3a' User entered 'None (0)'	System	10 Oct 2020 00:10:09
	System	10 Oct 2020 00:10:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:56:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-09T18:09:52', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '38c47bcb-84e2-400a-ac55-cf4c08912a3a' User entered 'None (0)'	System	10 Oct 2020 00:10:09
	System	10 Oct 2020 00:10:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:56:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-09T18:09:55', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '38c47bcb-84e2-400a-ac55-cf4c08912a3a' User entered 'None (0)'	System	10 Oct 2020 00:10:09
	System	10 Oct 2020 00:10:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:56:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-09T18:09:58', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '38c47bcb-84e2-400a-ac55-cf4c08912a3a' User entered 'None (0)'	System	10 Oct 2020 00:10:09
	System	10 Oct 2020 00:10:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:56:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-09T18:10:02', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '38c47bcb-84e2-400a-ac55-cf4c08912a3a' User entered 'None (0)'	System	10 Oct 2020 00:10:09
	System	10 Oct 2020 00:10:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-09T18:10:05', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '38c47bcb-84e2-400a-ac55-cf4c08912a3a' User entered 'No (N)'	System	10 Oct 2020 00:10:09
	System	10 Oct 2020 00:10:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:56:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-09T18:10:07', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '38c47bcb-84e2-400a-ac55-cf4c08912a3a'	System	10 Oct 2020 00:10:09
User entered '09 Oct 2020 18:10'	System	10 Oct 2020 00:10:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	07 Oct 2020 20:39:09
User entered 'Day 4'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:56:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T04:14:35', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '4f720b13-2b55-43c5-93d2-08da8f21a95f' User entered 'None (0)'	System	11 Oct 2020 10:15:07
	System	11 Oct 2020 10:15:07

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:56:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T04:14:50', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '4f720b13-2b55-43c5-93d2-08da8f21a95f' User entered 'No interference with activity (1)'	System	11 Oct 2020 10:15:07
	System	11 Oct 2020 10:15:07

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:56:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T04:14:53', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '4f720b13-2b55-43c5-93d2-08da8f21a95f' User entered 'None (0)'	System	11 Oct 2020 10:15:07
	System	11 Oct 2020 10:15:07

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:56:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T04:14:56', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '4f720b13-2b55-43c5-93d2-08da8f21a95f' User entered 'None (0)'	System	11 Oct 2020 10:15:07
	System	11 Oct 2020 10:15:07

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:56:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T04:14:58', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '4f720b13-2b55-43c5-93d2-08da8f21a95f' User entered 'None (0)'	System	11 Oct 2020 10:15:07
	System	11 Oct 2020 10:15:07

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:56:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T04:15:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '4f720b13-2b55-43c5-93d2-08da8f21a95f' User entered 'None (0)'	System	11 Oct 2020 10:15:07
	System	11 Oct 2020 10:15:07

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T04:15:03', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '4f720b13-2b55-43c5-93d2-08da8f21a95f' User entered 'No (N)'	System	11 Oct 2020 10:15:07
	System	11 Oct 2020 10:15:07

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:56:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T04:15:05', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '4f720b13-2b55-43c5-93d2-08da8f21a95f' User entered '11 Oct 2020 04:15'	System	11 Oct 2020 10:15:07
	System	11 Oct 2020 10:15:07

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	07 Oct 2020 20:39:09
User entered 'Day 5'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:56:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T21:17:09', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '3c70f585-3113-4661-b3c2-f4053c87f85e' User entered 'None (0)'	System	12 Oct 2020 03:17:28
	System	12 Oct 2020 03:17:28

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:56:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T21:17:12', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '3c70f585-3113-4661-b3c2-f4053c87f85e' User entered 'None (0)'	System	12 Oct 2020 03:17:28
	System	12 Oct 2020 03:17:28

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:56:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T21:17:15', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '3c70f585-3113-4661-b3c2-f4053c87f85e' User entered 'None (0)'	System	12 Oct 2020 03:17:28
	System	12 Oct 2020 03:17:28

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:56:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T21:17:17', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '3c70f585-3113-4661-b3c2-f4053c87f85e' User entered 'None (0)'	System	12 Oct 2020 03:17:28
	System	12 Oct 2020 03:17:28

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:56:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T21:17:19', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '3c70f585-3113-4661-b3c2-f4053c87f85e' User entered 'None (0)'	System	12 Oct 2020 03:17:28
	System	12 Oct 2020 03:17:28

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:56:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T21:17:21', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '3c70f585-3113-4661-b3c2-f4053c87f85e' User entered 'None (0)'	System	12 Oct 2020 03:17:28
	System	12 Oct 2020 03:17:28

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T21:17:24', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '3c70f585-3113-4661-b3c2-f4053c87f85e' User entered 'No (N)'	System	12 Oct 2020 03:17:28
	System	12 Oct 2020 03:17:28

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:56:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-11T21:17:26', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '3c70f585-3113-4661-b3c2-f4053c87f85e' User entered '11 Oct 2020 21:17'	System	12 Oct 2020 03:17:28
	System	12 Oct 2020 03:17:28

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	07 Oct 2020 20:39:09
User entered 'Day 6'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:56:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-12T17:15:52', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '226007c3-2483-4471-9446-9f52c45b6fce' User entered 'None (0)'	System	12 Oct 2020 23:16:15
	System	12 Oct 2020 23:16:15

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:56:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-12T17:15:54', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '226007c3-2483-4471-9446-9f52c45b6fce' User entered 'None (0)'	System	12 Oct 2020 23:16:15
	System	12 Oct 2020 23:16:15

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:56:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-12T17:15:56', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '226007c3-2483-4471-9446-9f52c45b6fce' User entered 'None (0)'	System	12 Oct 2020 23:16:15
	System	12 Oct 2020 23:16:15

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:56:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-12T17:15:58', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '226007c3-2483-4471-9446-9f52c45b6fce' User entered 'None (0)'	System	12 Oct 2020 23:16:15
	System	12 Oct 2020 23:16:15

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:56:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-12T17:16:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '226007c3-2483-4471-9446-9f52c45b6fce' User entered 'None (0)'	System	12 Oct 2020 23:16:15
	System	12 Oct 2020 23:16:15

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:56:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-12T17:16:01', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '226007c3-2483-4471-9446-9f52c45b6fce' User entered 'None (0)'	System	12 Oct 2020 23:16:15
	System	12 Oct 2020 23:16:15

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-12T17:16:03', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '226007c3-2483-4471-9446-9f52c45b6fce' User entered 'No (N)'	System	12 Oct 2020 23:16:15
	System	12 Oct 2020 23:16:15

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:56:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-12T17:16:05', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '226007c3-2483-4471-9446-9f52c45b6fce' User entered '12 Oct 2020 17:16'	System	12 Oct 2020 23:16:15
	System	12 Oct 2020 23:16:15

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
Data entry locked.	System	07 Oct 2020 20:39:09
User entered 'Day 7'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:56:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-13T21:26:22', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '536dbda6-7c83-4b09-be2e-eed72448ae9a' User entered 'None (0)'	System	14 Oct 2020 03:26:33
	System	14 Oct 2020 03:26:33

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:56:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-13T21:26:23', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '536dbda6-7c83-4b09-be2e-eed72448ae9a' User entered 'None (0)'	System	14 Oct 2020 03:26:33
	System	14 Oct 2020 03:26:33

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:56:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-13T21:26:25', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '536dbda6-7c83-4b09-be2e-eed72448ae9a' User entered 'None (0)'	System	14 Oct 2020 03:26:33
	System	14 Oct 2020 03:26:33

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:56:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-13T21:26:26', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '536dbda6-7c83-4b09-be2e-eed72448ae9a' User entered 'None (0)'	System	14 Oct 2020 03:26:33
	System	14 Oct 2020 03:26:33

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:56:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-13T21:26:27', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '536dbda6-7c83-4b09-be2e-eed72448ae9a' User entered 'None (0)'	System	14 Oct 2020 03:26:33
	System	14 Oct 2020 03:26:33

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:56:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-13T21:26:28', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '536dbda6-7c83-4b09-be2e-eed72448ae9a' User entered 'None (0)'	System	14 Oct 2020 03:26:33
	System	14 Oct 2020 03:26:33

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-13T21:26:29', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '536dbda6-7c83-4b09-be2e-eed72448ae9a' User entered 'No (N)'	System	14 Oct 2020 03:26:33
	System	14 Oct 2020 03:26:33

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:56:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-10-13T21:26:31', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '536dbda6-7c83-4b09-be2e-eed72448ae9a' User entered '13 Oct 2020 21:26'	System	14 Oct 2020 03:26:33
	System	14 Oct 2020 03:26:33

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:56:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 20:39:09

US3502125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:56:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:39:45
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 20:39:09

US3502125

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Patrishia Adkins (b) (4)	15 Oct 2020 23:25:11

US3502125

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '15 Oct 2020'	Patrishia Adkins (b) (4)	15 Oct 2020 23:25:11

US3502125

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Contact Made (CONTACT MADE)'	Patrishia Adkins (b) (4)	15 Oct 2020 23:25:11

US3502125

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	(b) (4) Patrisha Adkins (b) (4)	15 Oct 2020 23:25:11

US3502125

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Patrishia Adkins (b) (4)	15 Oct 2020 23:25:16

US3502125

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User entered '1'	System	15 Oct 2020 23:25:16

US3502125

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Patrishia Adkins (b) (4)	22 Oct 2020 20:28:57

US3502125

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '22 Oct 2020'	Patrishia Adkins (b) (4)	22 Oct 2020 20:28:57

US3502125

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Contact Made (CONTACT MADE)'	Patrishia Adkins (b) (4)	22 Oct 2020 20:28:57

US3502125

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	(b) (4) Patrisha Adkins (b) (4)	22 Oct 2020 20:28:57

US3502125

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Patrishia Adkins (b) (4)	22 Oct 2020 20:29:02

US3502125

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User entered '1'	System	22 Oct 2020 20:29:02

US3502125

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Patrishia Adkins (b) (4)	28 Oct 2020 20:12:46

US3502125

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '28 Oct 2020'	Patrishia Adkins (b) (4)	28 Oct 2020 20:12:46

US3502125

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Contact Made (CONTACT MADE)'	Patrishia Adkins (b) (4)	28 Oct 2020 20:12:46

US3502125

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	(b) (4) Patrisha Adkins (b) (4)	28 Oct 2020 20:12:46

US3502125

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Patrishia Adkins (b) (4)	28 Oct 2020 20:12:51

US3502125

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User entered '1'	System	28 Oct 2020 20:12:51

US3502125

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:56:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:48:53

US3502125

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '06 Nov 2020'	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:48:53

US3502125

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered 'Clinic (Clinic)'	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:48:53

US3502125

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:56:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered 'VISIT3'	System	06 Nov 2020 17:48:53

US3502125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:49:56

US3502125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '06 Nov 2020'	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:49:56

US3502125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '10:09'	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:49:56

US3502125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered '06 Nov 2020 10:09'	System	06 Nov 2020 17:49:56

US3502125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '36.2' C	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:49:56

US3502125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered 'Other (Other)'	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:49:56

US3502125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered 'temporal'	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:49:56

US3502125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '95'	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:49:56

US3502125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered 'bpm'	System	06 Nov 2020 17:49:56

US3502125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '14'	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:49:56

US3502125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered 'breaths/min'	System	06 Nov 2020 17:49:56

US3502125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User closed query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 03:21:18
Query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate' answered with 'NCS' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 00:34:08
User opened query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 05:41:39
User entered '158'	Suzanne Fiorillo (b) (4) (b) (4)	06 Nov 2020 17:49:56

US3502125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered 'mmHg'	System	06 Nov 2020 17:49:56

US3502125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '96'	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:49:56

US3502125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered 'mmHg'	System	06 Nov 2020 17:49:56

US3502125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15

US3502125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15

US3502125

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:56:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Dec 2020 22:13:12
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4) (b) (4)	06 Nov 2020 17:49:03

US3502125

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:56:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Dec 2020 22:13:12
User entered '06 Nov 2020'	Suzanne Fiorillo (b) (4) (b) (4)	06 Nov 2020 17:49:03

US3502125

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:50:17

US3502125

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '06 Nov 2020'	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:50:17

US3502125

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered '10:25'	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:50:17

US3502125

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered '06 Nov 2020 10:25'	System	06 Nov 2020 17:50:17

US3502125

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:46:38
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:49:10

US3502125

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:15
User entered '1'	System	06 Nov 2020 17:49:10

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44
Data entry locked.	System	09 Sep 2020 20:51:21
User entered 'Day 64'	System	09 Sep 2020 20:51:21

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44
Data entry locked.	System	09 Sep 2020 20:51:21
User entered '09 Nov 2020 00:01'	System	09 Sep 2020 20:51:21

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44
Data entry locked.	System	09 Sep 2020 20:51:21
User entered '13 Nov 2020 23:59'	System	09 Sep 2020 20:51:21

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44
Data entry locked.	System	09 Sep 2020 20:51:21
User entered 'Day 71'	System	09 Sep 2020 20:51:21

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44
Data entry locked.	System	09 Sep 2020 20:51:21
User entered '16 Nov 2020 00:01'	System	09 Sep 2020 20:51:21

US3502125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:51:44
Data entry locked.	System	09 Sep 2020 20:51:21
User entered '20 Nov 2020 23:59'	System	09 Sep 2020 20:51:21

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-12-07T07:26:21', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '5dd00de2-faa9-4240-afe5-882f59778009'	System	07 Dec 2020 14:26:40
User entered 'No (N)'	System	07 Dec 2020 14:26:40

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Have you been exposed to someone with 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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-12-07T07:26:24', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '5dd00de2-faa9-4240-afe5-882f59778009'	System	07 Dec 2020 14:26:40
User entered 'No (N)'	System	07 Dec 2020 14:26:40

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-12-07T07:26:38', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '5dd00de2-faa9-4240-afe5-882f59778009'	System	07 Dec 2020 14:26:40
User entered '07 Dec 2020 07:26:38'	System	07 Dec 2020 14:26:40

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-12-11T08:49:23', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'a0479398-02ac-4e46-bb24-23fb4a306683' User entered 'No (N)'	System	11 Dec 2020 15:49:32
	System	11 Dec 2020 15:49:32

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Have you been exposed to someone with 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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-12-11T08:49:26', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'a0479398-02ac-4e46-bb24-23fb4a306683'	System	11 Dec 2020 15:49:32
User entered 'No (N)'	System	11 Dec 2020 15:49:32

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-12-11T08:49:29', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'a0479398-02ac-4e46-bb24-23fb4a306683'	System	11 Dec 2020 15:49:32
User entered '11 Dec 2020 08:49:29'	System	11 Dec 2020 15:49:32

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-12-20T12:14:24', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'd104ee03-ba60-46be-bae8-f788f225d1e3'	System	20 Dec 2020 19:14:32
User entered 'No (N)'	System	20 Dec 2020 19:14:32

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Have you been exposed to someone with 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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-12-20T12:14:26', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'd104ee03-ba60-46be-bae8-f788f225d1e3'	System	20 Dec 2020 19:14:32
User entered 'No (N)'	System	20 Dec 2020 19:14:32

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-12-20T12:14:29', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'd104ee03-ba60-46be-bae8-f788f225d1e3'	System	20 Dec 2020 19:14:32
User entered '20 Dec 2020 12:14:29'	System	20 Dec 2020 19:14:32

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-12-25T02:40:57', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '075e9b7f-c675-419c-ba84-a7c34700597b' User entered 'No (N)'	System	25 Dec 2020 09:41:48
	System	25 Dec 2020 09:41:48

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Have you been exposed to someone with 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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-12-25T02:41:03', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '075e9b7f-c675-419c-ba84-a7c34700597b' User entered 'Yes (Y)'	System	25 Dec 2020 09:41:48
	System	25 Dec 2020 09:41:48

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Please 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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-12-25T02:41:22', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '075e9b7f-c675-419c-ba84-a7c34700597b'	System	25 Dec 2020 09:41:48
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Dec 2020 09:41:48

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2020-12-25T02:41:37', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '075e9b7f-c675-419c-ba84-a7c34700597b' User entered '25 Dec 2020 02:41:37'	System	25 Dec 2020 09:41:48
	System	25 Dec 2020 09:41:48

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-01-01T00:49:34', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'e2474f68-9efc-44ed-8cc2-bbf2c34aac38'	System	01 Jan 2021 07:49:47
User entered 'No (N)'	System	01 Jan 2021 07:49:47

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Have you been exposed to someone with 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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-01-01T00:49:41', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'e2474f68-9efc-44ed-8cc2-bbf2c34aac38'	System	01 Jan 2021 07:49:47
User entered 'No (N)'	System	01 Jan 2021 07:49:47

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-01-01T00:49:45', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'e2474f68-9efc-44ed-8cc2-bbf2c34aac38' User entered '01 Jan 2021 00:49:45'	System	01 Jan 2021 07:49:47
	System	01 Jan 2021 07:49:47

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-01-08T21:40:26', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'ebdfe46d-124b-4b9f-b84e-91306fc2ac6a'	System	09 Jan 2021 02:40:36
User entered 'No (N)'	System	09 Jan 2021 02:40:36

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Have you been exposed to someone with 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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-01-08T21:40:28', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'ebdfe46d-124b-4b9f-b84e-91306fc2ac6a'	System	09 Jan 2021 02:40:36
User entered 'No (N)'	System	09 Jan 2021 02:40:36

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-01-08T21:40:31', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'ebdfe46d-124b-4b9f-b84e-91306fc2ac6a' User entered '08 Jan 2021 21:40:31'	System	09 Jan 2021 02:40:36

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-01-15T21:32:41', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '8bf91d49-2823-4a28-a126-589527f886c6'	System	16 Jan 2021 04:32:50
User entered 'No (N)'	System	16 Jan 2021 04:32:50

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Have you been exposed to someone with 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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-01-15T21:32:43', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '8bf91d49-2823-4a28-a126-589527f886c6'	System	16 Jan 2021 04:32:50
User entered 'No (N)'	System	16 Jan 2021 04:32:50

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-01-15T21:32:47', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '8bf91d49-2823-4a28-a126-589527f886c6' User entered '15 Jan 2021 21:32:47'	System	16 Jan 2021 04:32:50
	System	16 Jan 2021 04:32:50

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-01-22T04:02:28', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '52dcbe9a-31ed-4fa3-b2e3-8b904387abc6'	System	22 Jan 2021 11:02:40
User entered 'No (N)'	System	22 Jan 2021 11:02:40

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Have you been exposed to someone with 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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-01-22T04:02:31', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '52dcbe9a-31ed-4fa3-b2e3-8b904387abc6'	System	22 Jan 2021 11:02:40
User entered 'No (N)'	System	22 Jan 2021 11:02:40

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-01-22T04:02:36', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '52dcbe9a-31ed-4fa3-b2e3-8b904387abc6'	System	22 Jan 2021 11:02:40
User entered '22 Jan 2021 04:02:36'	System	22 Jan 2021 11:02:40

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-01-29T08:53:04', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'f0105aac-3d63-4484-a907-e11e6920fb71'	System	29 Jan 2021 15:53:11
User entered 'No (N)'	System	29 Jan 2021 15:53:11

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Have you been exposed to someone with 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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-01-29T08:53:06', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'f0105aac-3d63-4484-a907-e11e6920fb71'	System	29 Jan 2021 15:53:11
User entered 'No (N)'	System	29 Jan 2021 15:53:11

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-01-29T08:53:09', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'f0105aac-3d63-4484-a907-e11e6920fb71' User entered '29 Jan 2021 08:53:09'	System	29 Jan 2021 15:53:11
	System	29 Jan 2021 15:53:11

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-02-05T08:27:10', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '9b4a6c65-1c2a-4fa3-a666-522dcefc67ad'	System	05 Feb 2021 15:27:21
User entered 'No (N)'	System	05 Feb 2021 15:27:21

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Have you been exposed to someone with 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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-02-05T08:27:15', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '9b4a6c65-1c2a-4fa3-a666-522dcefc67ad'	System	05 Feb 2021 15:27:21
User entered 'No (N)'	System	05 Feb 2021 15:27:21

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-02-05T08:27:18', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '9b4a6c65-1c2a-4fa3-a666-522dcefc67ad'	System	05 Feb 2021 15:27:21
User entered '05 Feb 2021 08:27:18'	System	05 Feb 2021 15:27:21

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-02-12T01:59:44', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '7c61c93f-cc4e-4050-b114-0286cc2095a2'	System	12 Feb 2021 08:59:52
User entered 'No (N)'	System	12 Feb 2021 08:59:52

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Have you been exposed to someone with 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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-02-12T01:59:47', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '7c61c93f-cc4e-4050-b114-0286cc2095a2'	System	12 Feb 2021 08:59:52
User entered 'No (N)'	System	12 Feb 2021 08:59:52

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-02-12T01:59:50', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '7c61c93f-cc4e-4050-b114-0286cc2095a2'	System	12 Feb 2021 08:59:52
User entered '12 Feb 2021 01:59:50'	System	12 Feb 2021 08:59:52

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-02-21T12:03:25', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '502251dc-a376-475f-a1c5-60ea4563f20f'	System	21 Feb 2021 19:03:34
User entered 'No (N)'	System	21 Feb 2021 19:03:34

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Have you been exposed to someone with 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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-02-21T12:03:29', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '502251dc-a376-475f-a1c5-60ea4563f20f' User entered 'No (N)'	System	21 Feb 2021 19:03:34
	System	21 Feb 2021 19:03:34

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-02-21T12:03:31', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '502251dc-a376-475f-a1c5-60ea4563f20f' User entered '21 Feb 2021 12:03:31'	System	21 Feb 2021 19:03:34
	System	21 Feb 2021 19:03:34

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-02-26T00:28:17-07:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '44e66929-cc67-4d46-84b0-66c31f923180'	System	26 Feb 2021 07:28:34
User entered 'No (N)'	System	26 Feb 2021 07:28:34

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Have you been exposed to someone with 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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-02-26T00:28:20-07:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '44e66929-cc67-4d46-84b0-66c31f923180'	System	26 Feb 2021 07:28:34
User entered 'No (N)'	System	26 Feb 2021 07:28:34

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-02-26T00:28:29-07:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '44e66929-cc67-4d46-84b0-66c31f923180'	System	26 Feb 2021 07:28:34
User entered '26 Feb 2021 07:28:29'	System	26 Feb 2021 07:28:34

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-03-05T07:59:35-07:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'c0d13921-6255-44ae-a311-6b58afab5619'	System	05 Mar 2021 14:59:44
User entered 'No (N)'	System	05 Mar 2021 14:59:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Have you been exposed to someone with 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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-03-05T07:59:37-07:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'c0d13921-6255-44ae-a311-6b58afab5619'	System	05 Mar 2021 14:59:44
User entered 'No (N)'	System	05 Mar 2021 14:59:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-03-05T07:59:42-07:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'c0d13921-6255-44ae-a311-6b58afab5619' User entered '05 Mar 2021 07:59:42'	System	05 Mar 2021 14:59:44
	System	05 Mar 2021 14:59:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-03-12T00:02:24-07:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'e49a62c5-f382-4faf-ba8c-69fc30a43a38'	System	12 Mar 2021 07:02:39
User entered 'No (N)'	System	12 Mar 2021 07:02:39

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Have you been exposed to someone with 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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-03-12T00:02:32-07:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'e49a62c5-f382-4faf-ba8c-69fc30a43a38'	System	12 Mar 2021 07:02:39
User entered 'No (N)'	System	12 Mar 2021 07:02:39

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-03-12T00:02:36-07:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'e49a62c5-f382-4faf-ba8c-69fc30a43a38'	System	12 Mar 2021 07:02:39
User entered '12 Mar 2021 00:02:36'	System	12 Mar 2021 07:02:39

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-03-22T20:57:56-06:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'd9505ea1-d307-432a-96a0-0d901d503d3f'	System	23 Mar 2021 02:58:08
User entered 'No (N)'	System	23 Mar 2021 02:58:08

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Have you been exposed to someone with 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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-03-22T20:57:58-06:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'd9505ea1-d307-432a-96a0-0d901d503d3f'	System	23 Mar 2021 02:58:08
User entered 'No (N)'	System	23 Mar 2021 02:58:08

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-03-22T20:58:01-06:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: 'd9505ea1-d307-432a-96a0-0d901d503d3f' User entered '22 Mar 2021 20:58:01'	System	23 Mar 2021 02:58:08
	System	23 Mar 2021 02:58:08

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-03-29T17:59:19-04:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '863bb197-465f-402d-8917-9bed6202fac3'	System	29 Mar 2021 21:59:28
User entered 'No (N)'	System	29 Mar 2021 21:59:28

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Have you been exposed to someone with 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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-03-29T17:59:21-04:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '863bb197-465f-402d-8917-9bed6202fac3'	System	29 Mar 2021 21:59:28
User entered 'No (N)'	System	29 Mar 2021 21:59:28

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-03-29T17:59:25-04:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '863bb197-465f-402d-8917-9bed6202fac3'	System	29 Mar 2021 21:59:28
User entered '29 Mar 2021 17:59:25'	System	29 Mar 2021 21:59:28

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-04-02T09:21:55-06:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '14d8367a-49db-4140-9a73-3c8e8e087e85'	System	02 Apr 2021 15:22:03
User entered 'No (N)'	System	02 Apr 2021 15:22:03

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Have you been exposed to someone with 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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-04-02T09:21:58-06:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '14d8367a-49db-4140-9a73-3c8e8e087e85'	System	02 Apr 2021 15:22:03
User entered 'No (N)'	System	02 Apr 2021 15:22:03

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-04-02T09:22:00-06:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '14d8367a-49db-4140-9a73-3c8e8e087e85'	System	02 Apr 2021 15:22:03
User entered '02 Apr 2021 09:22:00'	System	02 Apr 2021 15:22:03

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-04-11T12:06:14-06:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '9e231db7-ddab-4269-897f-f5251bb0a142'	System	11 Apr 2021 18:06:25
User entered 'No (N)'	System	11 Apr 2021 18:06:25

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Have you been exposed to someone with 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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-04-11T12:06:17-06:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '9e231db7-ddab-4269-897f-f5251bb0a142'	System	11 Apr 2021 18:06:25
User entered 'No (N)'	System	11 Apr 2021 18:06:25

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-04-11T12:06:20-06:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '9e231db7-ddab-4269-897f-f5251bb0a142'	System	11 Apr 2021 18:06:25
User entered '11 Apr 2021 12:06:20'	System	11 Apr 2021 18:06:25

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-04-16T08:33:09-06:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '3dd03dcd-544c-427f-b0c4-285092a13f46'	System	26 Apr 2021 06:35:45
User entered 'Yes (Y)'	System	26 Apr 2021 06:35:45

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Have you been exposed to someone with 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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-04-16T08:33:15-06:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '3dd03dcd-544c-427f-b0c4-285092a13f46'	System	26 Apr 2021 06:35:45
User entered 'No (N)'	System	26 Apr 2021 06:35:45

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-04-16T08:33:19-06:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '3dd03dcd-544c-427f-b0c4-285092a13f46'	System	26 Apr 2021 06:35:45
User entered 'No (N)'	System	26 Apr 2021 06:35:45

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-04-16T08:33:24-06:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '3dd03dcd-544c-427f-b0c4-285092a13f46'	System	26 Apr 2021 06:35:45
User entered 'Yes (Y)'	System	26 Apr 2021 06:35:45

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Please 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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-04-16T08:33:29-06:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '3dd03dcd-544c-427f-b0c4-285092a13f46'	System	26 Apr 2021 06:35:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Apr 2021 06:35:45

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-04-16T08:33:32-06:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '3dd03dcd-544c-427f-b0c4-285092a13f46'	System	26 Apr 2021 06:35:45
User entered '16 Apr 2021 08:33:32'	System	26 Apr 2021 06:35:45

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-04-26T00:35:38-06:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '271b3f6b-89d1-47c6-a392-ae1f1cf7346b'	System	26 Apr 2021 06:35:47
User entered 'No (N)'	System	26 Apr 2021 06:35:47

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Have you been exposed to someone with 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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-04-26T00:35:41-06:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '271b3f6b-89d1-47c6-a392-ae1f1cf7346b'	System	26 Apr 2021 06:35:47
User entered 'No (N)'	System	26 Apr 2021 06:35:47

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-04-26T00:35:44-06:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '271b3f6b-89d1-47c6-a392-ae1f1cf7346b'	System	26 Apr 2021 06:35:47
User entered '26 Apr 2021 00:35:44'	System	26 Apr 2021 06:35:47

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-04-30T00:02:32-06:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '12c084db-e13e-4604-812f-dbd5a9dcc65c'	System	30 Apr 2021 06:02:42
User entered 'No (N)'	System	30 Apr 2021 06:02:42

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

Have you been exposed to someone with 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 (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-04-30T00:02:36-06:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '12c084db-e13e-4604-812f-dbd5a9dcc65c'	System	30 Apr 2021 06:02:42
User entered 'No (N)'	System	30 Apr 2021 06:02:42

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-04-30T00:02:39-06:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '12c084db-e13e-4604-812f-dbd5a9dcc65c'	System	30 Apr 2021 06:02:42
User entered '30 Apr 2021 00:02:39'	System	30 Apr 2021 06:02:42

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 06:51:44

US3502125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:51:44
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 06:51:44

US3502125

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 07:56:49

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-03-05T07:59:46-07:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '8ac8ff01-5c18-45ae-bb02-ebff95b79f0b'	System	05 Mar 2021 14:59:52
User entered 'No (N)'	System	05 Mar 2021 14:59:52

US3502125

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 07:56:49

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB0766FF-EFED-430A-B4AC-688D0C6D56F4)', Time: '2021-03-05T07:59:50-07:00', User OID: 'PatientReportedOutcome (US3502125)', ODM File OID: '8ac8ff01-5c18-45ae-bb02-ebff95b79f0b' User entered '05 Mar 2021 07:59:50'	System	05 Mar 2021 14:59:52
	System	05 Mar 2021 14:59:52

US3502125

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Patrishia Adkins (b) (4)	03 Dec 2020 23:47:22

US3502125

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '3 Dec 2020'	Patrishia Adkins (b) (4)	03 Dec 2020 23:47:22

US3502125

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Contact Made (CONTACT MADE)'	Patrishia Adkins (b) (4)	03 Dec 2020 23:47:22

US3502125

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	(b) (4) Patrisha Adkins (b) (4)	03 Dec 2020 23:47:22
	(b) (4)	

US3502125

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Patrishia Adkins (b) (4)	03 Dec 2020 23:47:27

US3502125

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:28:10
User entered '1'	System	03 Dec 2020 23:47:27

US3502125

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:35:05
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 21:12:20

US3502125

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:35:05
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '7 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 21:12:20

US3502125

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:35:05
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 21:12:20

US3502125

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:35:05
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 21:12:20

US3502125

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:35:05
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 21:12:27

US3502125

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:35:05
User entered '1'	System	08 Jan 2021 21:12:27

US3502125

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:35:05
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Laurel Ware (b) (4)	03 Feb 2021 20:52:34

US3502125

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:35:05
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '03 Feb 2021'	Laurel Ware (b) (4)	03 Feb 2021 20:52:34

US3502125

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:35:05
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Contact Made (CONTACT MADE)'	Laurel Ware (b) (4)	03 Feb 2021 20:52:34

US3502125

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:35:05
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered empty.	(b) (4) Laurel Ware (b) (4) (b) (4)	03 Feb 2021 20:52:34

US3502125

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:35:05
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Laurel Ware (b) (4)	03 Feb 2021 20:52:21

US3502125

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:35:05
User entered '1'	System	03 Feb 2021 20:52:21

US3502125

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:03
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:06:29
User entered 'Yes (Y)'	Laurel Ware (b) (4)	23 Mar 2021 21:40:14

US3502125

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:03
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:06:29
User entered '06 Mar 2021'	Laurel Ware (b) (4)	23 Mar 2021 21:40:14

US3502125

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:03
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:06:29
User entered 'Contact Made (CONTACT MADE)'	Laurel Ware (b) (4)	23 Mar 2021 21:40:14

US3502125

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:03
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:06:29
User entered empty.	(b) (4) Laurel Ware (b) (4)	23 Mar 2021 21:40:14
	(b) (4)	

US3502125

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:03
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:06:29
User entered 'Yes (Y)'	Laurel Ware (b) (4)	23 Mar 2021 21:40:22

US3502125

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:03
User entered 'I'	System	23 Mar 2021 21:40:22

US3502125

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:56:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:45
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:06:29
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	05 Apr 2021 23:01:17

US3502125

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:45
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:06:29
User entered '05 Apr 2021'	Suzanne Fiorillo (b) (4)	05 Apr 2021 23:01:17

US3502125

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:45
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:06:29
User entered 'Clinic (Clinic)'	Suzanne Fiorillo (b) (4)	05 Apr 2021 23:01:17

US3502125

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:56:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:45
User entered 'VISIT4'	System	05 Apr 2021 23:01:17

US3502125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:45
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:06:29
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	05 Apr 2021 23:01:04

US3502125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:45
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:06:29
User entered '05 Apr 2021'	Suzanne Fiorillo (b) (4)	05 Apr 2021 23:01:04

US3502125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:45
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:06:29
User entered '12:55'	Suzanne Fiorillo (b) (4)	05 Apr 2021 23:01:04

US3502125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:45
User entered '05 Apr 2021 12:55'	System	05 Apr 2021 23:01:04

US3502125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:45
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:06:29
User entered '36.5' C	Suzanne Fiorillo (b) (4)	05 Apr 2021 23:01:04

US3502125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:45
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:06:29
User entered 'Other (Other)'	Suzanne Fiorillo (b) (4)	05 Apr 2021 23:01:04

US3502125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:45
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:06:29
User entered 'temporal'	Suzanne Fiorillo (b) (4)	05 Apr 2021 23:01:04

US3502125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:45
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:06:29
User entered '70'	Suzanne Fiorillo (b) (4)	05 Apr 2021 23:01:04

US3502125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:45
User entered 'bpm'	System	05 Apr 2021 23:01:04

US3502125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:45
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:06:29
User entered '12'	Suzanne Fiorillo (b) (4)	05 Apr 2021 23:01:04

US3502125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:45
User entered 'breaths/min'	System	05 Apr 2021 23:01:04

US3502125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:45
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:06:29
User entered '148'	Suzanne Fiorillo (b) (4)	05 Apr 2021 23:01:04

US3502125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:45
User entered 'mmHg'	System	05 Apr 2021 23:01:04

US3502125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:45
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:06:29
User entered '86'	Suzanne Fiorillo (b) (4)	05 Apr 2021 23:01:04

US3502125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:45
User entered 'mmHg'	System	05 Apr 2021 23:01:04

US3502125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:45

US3502125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:49

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:45

US3502125

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:56:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:45
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:06:29
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	05 Apr 2021 23:00:38

US3502125

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:56:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:45
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:06:29
User entered '05 Apr 2021'	Suzanne Fiorillo (b) (4)	05 Apr 2021 23:00:38

US3502125

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:45
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:06:29
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	05 Apr 2021 23:00:29

US3502125

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:45
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:06:29
User entered '05 Apr 2021'	Suzanne Fiorillo (b) (4)	05 Apr 2021 23:00:29

US3502125

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:45
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:06:29
User entered '13:15'	Suzanne Fiorillo (b) (4)	05 Apr 2021 23:00:29

US3502125

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:45
User entered '05 Apr 2021 13:15'	System	05 Apr 2021 23:00:29

US3502125

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:45
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:06:29
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	05 Apr 2021 23:00:08

US3502125

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:45
User entered '1'	System	05 Apr 2021 23:00:08

US3502125

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

Form: Visit Date

Generated On: 10 Jun 2021 07:56:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	(b) (4) Suzanne Fiorillo (b) (4)	12 Jan 2021 23:23:22
	(b) (4)	

US3502125

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

Form: Visit Date

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '12 Jan 2021'	Suzanne Fiorillo (b) (4)	12 Jan 2021 23:23:22

US3502125

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

Form: Visit Date

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Clinic (Clinic)'	Suzanne Fiorillo (b) (4)	12 Jan 2021 23:23:22

US3502125

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

Form: Visit Date

Generated On: 10 Jun 2021 07:56:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User entered 'UNBLND_DECIDE'	System	12 Jan 2021 23:23:22

US3502125

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

Form: Unblinding

Generated On: 10 Jun 2021 07:56:49

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '12 Jan 2021'	(b) (4) Suzanne Fiorillo (b) (4)	12 Jan 2021 23:25:49

US3502125

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

Form: Unblinding

Generated On: 10 Jun 2021 07:56:49

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:00:17

US3502125

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

Form: Unblinding

Generated On: 10 Jun 2021 07:56:49

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	(b) (4) Suzanne Fiorillo (b) (4)	12 Jan 2021 23:25:49

US3502125

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

Form: Unblinding

Generated On: 10 Jun 2021 07:56:49

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:00:17

US3502125

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

Form: Unblinding

Generated On: 10 Jun 2021 07:56:49

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '12 Jan 2021'	Suzanne Fiorillo (b) (4)	12 Jan 2021 23:25:49

US3502125

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

Form: Unblinding

Generated On: 10 Jun 2021 07:56:49

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'mRNA-1273 (mRNA-1273)'	Suzanne Fiorillo (b) (4)	12 Jan 2021 23:25:49

US3502125

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

Form: Unblinding

Generated On: 10 Jun 2021 07:56:49

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 14:34:10
User entered 'mRNA-1273 (mRNA-1273)'	Suzanne Fiorillo (b) (4) (b) (4)	12 Jan 2021 23:25:49

US3502125

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

Form: Unblinding

Generated On: 10 Jun 2021 07:56:49

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 14:34:10
User entered 'mRNA-1273 (mRNA-1273)'	Suzanne Fiorillo (b) (4) (b) (4)	12 Jan 2021 23:25:49

US3502125

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

Form: Unblinding

Generated On: 10 Jun 2021 07:56:49

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'No (N)'	Suzanne Fiorillo (b) (4)	12 Jan 2021 23:25:49

US3502125

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

Form: Unblinding

Generated On: 10 Jun 2021 07:56:49

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User entered empty.	System	12 Jan 2021 23:25:49

US3502125

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

Form: Unblinding

Generated On: 10 Jun 2021 07:56:49

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User entered empty.	System	12 Jan 2021 23:25:49

US3502125

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	12 Jan 2021 23:26:10

US3502125

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '12 Jan 2021'	(b) (4) Suzanne Fiorillo (b) (4)	12 Jan 2021 23:26:10

US3502125

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '14:17'	Suzanne Fiorillo (b) (4)	12 Jan 2021 23:26:10

US3502125

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User entered '12 Jan 2021 14:17'	System	12 Jan 2021 23:26:10

US3502125

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:56:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	12 Jan 2021 23:26:25

US3502125

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:56:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '12 Jan 2021'	Suzanne Fiorillo (b) (4)	12 Jan 2021 23:26:25

US3502125

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:56:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered '14:24'	Suzanne Fiorillo (b) (4)	12 Jan 2021 23:26:25

US3502125

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:08:53
User entered '12 Jan 2021 14:24'	System	12 Jan 2021 23:26:25

US3502125

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 07:56:49

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:38
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Signature has been broken.	Laurel Ware (b) (4)	21 Apr 2021 22:20:33
User entered 'Yes (Y)' reason for change: New Information	Laurel Ware (b) (4)	21 Apr 2021 22:20:33
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'No (N)'	Suzanne Fiorillo (b) (4)	08 Feb 2021 21:31:32

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:43
User entered 'USA-US080-2021-mRNA-1273-P301000001'	System	22 Apr 2021 13:32:36
User entered 'New'	(b) (4), (b) (6)	22 Apr 2021 13:32:36

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User coded data point as SOC: Nervous system disorders, HLG: Mental impairment disorders, HLT: Memory loss (excl dementia), PT: Transient global amnesia, LLT: Transient global amnesia - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 22:29:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 22:29:41
Data point term sent to Coder	System	21 Apr 2021 22:28:57
User entered 'transient global amnesia'	Laurel Ware (b) (4)	21 Apr 2021 22:28:51

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
	(b) (4)	
User entered 'Yes (Y)'	Laurel Ware (b) (4)	21 Apr 2021 22:28:51
	(b) (4)	

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered 'No (N)'	(b) (4) Laurel Ware (b) (4)	21 Apr 2021 22:28:51
	(b) (4)	

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
	(b) (4)	
User entered 'No (N)'	Laurel Ware (b) (4)	21 Apr 2021 22:28:51
	(b) (4)	

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
	(b) (4)	
User entered '09 Apr 2021'	Laurel Ware (b) (4)	21 Apr 2021 22:28:51
	(b) (4)	

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered empty.	(b) (4) Laurel Ware (b) (4)	21 Apr 2021 22:28:51
	(b) (4)	

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 22:28:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 16:14:26
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)	29 Apr 2021 16:14:16
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered 'Yes (Y)' reason for change: New Information	(b) (4) Laurel Ware (b) (4)	22 Apr 2021 21:08:44
User entered 'No (N)'	Laurel Ware (b) (4)	21 Apr 2021 22:28:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	22 Apr 2021 21:09:06
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	22 Apr 2021 21:09:06
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	22 Apr 2021 21:08:44
User entered empty; reason for change New Information	Laurel Ware (b) (4)	22 Apr 2021 21:08:44
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	21 Apr 2021 22:29:14
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	21 Apr 2021 22:29:14
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	21 Apr 2021 22:28:51
User entered '10 Apr 2021'	Laurel Ware (b) (4)	21 Apr 2021 22:28:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
	(b) (4)	
User entered empty.	Laurel Ware (b) (4)	21 Apr 2021 22:28:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 22:28:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Laurel Ware (b) (4) (b) (4)	21 Apr 2021 22:28:51

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
	(b) (4)	
User entered 'Yes (Y)'	Laurel Ware (b) (4)	21 Apr 2021 22:28:51
	(b) (4)	

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered '0'	(b) (4) Laurel Ware (b) (4) (b) (4)	21 Apr 2021 22:28:51

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered '0'	(b) (4) Laurel Ware (b) (4) (b) (4)	21 Apr 2021 22:28:51

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered 'I'	(b) (4) Laurel Ware (b) (4) (b) (4)	21 Apr 2021 22:28:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
	(b) (4)	
User entered '09 Apr 2021'	Laurel Ware (b) (4)	21 Apr 2021 22:28:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered '10 Apr 2021'	(b) (4) Laurel Ware (b) (4) (b) (4)	21 Apr 2021 22:28:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Laurel Ware (b) (4)	22 Apr 2021 21:08:44
	(b) (4)	
User entered 'No (N)'	Laurel Ware (b) (4)	21 Apr 2021 22:28:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered '1' reason for change: New Information	(b) (4)	22 Apr 2021 21:08:44
User entered empty.	Laurel Ware (b) (4)	21 Apr 2021 22:28:51
	(b) (4)	

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
	(b) (4)	
User entered '0'	Laurel Ware (b) (4)	21 Apr 2021 22:28:51
	(b) (4)	

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered '0'	(b) (4) Laurel Ware (b) (4)	21 Apr 2021 22:28:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered '0'	(b) (4) Laurel Ware (b) (4) (b) (4)	21 Apr 2021 22:28:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered 'Not Related (NOT RELATED)'	(b) (4) Laurel Ware (b) (4)	21 Apr 2021 22:28:51
	(b) (4)	

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered 'Not Related (NOT RELATED)'	(b) (4) Laurel Ware (b) (4)	21 Apr 2021 22:28:51
	(b) (4)	

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Laurel Ware (b) (4)	21 Apr 2021 22:28:51
	(b) (4)	

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered '0'	(b) (4) Laurel Ware (b) (4) (b) (4)	21 Apr 2021 22:28:51

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
	(b) (4)	
User entered 'I'	Laurel Ware (b) (4)	21 Apr 2021 22:28:51
	(b) (4)	

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered '1' reason for change: New Information	(b) (4)	22 Apr 2021 21:08:44
User entered '0'	Laurel Ware (b) (4)	21 Apr 2021 22:28:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	(b) (4) Laurel Ware (b) (4)	22 Apr 2021 21:09:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Laurel Ware (b) (4)	21 Apr 2021 22:29:14
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Laurel Ware (b) (4)	21 Apr 2021 22:28:51

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
	(b) (4)	
User entered empty.	Laurel Ware (b) (4)	21 Apr 2021 22:28:51
	(b) (4)	

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

[Narrative](#)

Audit	User	Time (GMT)
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)	29 Apr 2021 16:14:40
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 16:14:34
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 16:14:04
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

[Narrative](#)

Audit	User	Time (GMT)
User entered 'STUDY STAFF WAS NOTIFIED 20APR2021, WE ARE ATTEMPTING TO GATHER MORE INFORMATION AT THIS POINT. THIS AE REQUIRED A TEMPORARY MEDICATION OF LISINOPRIL. START DATES AND END DATES MAY CHANGE. added 22APR2021 On 20APR2021 Site staff was notified by subject that she had a hospital admission on 09APR2021 through 10APR2021. She states she was taken to the Emergency Department on 09APR2021 by her husband and was admitted to the ICU. Her symptoms were disorientation, not being able to remember anything, for any amount of time, and unable to follow simple instructions. Subject also reported that her blood pressure on presentation to the ED was 205/117 mmhg with blood pressures returning to normal prior to discharge. ED visit differential diagnosis considered included but not limited to TIA, CVA, transient global amnesia, hypertensive emergency, anxiety. Lab results show no leukocytosis or anemia, no significant electrolyte abnormality or renal failure, heart normal, troponin negative. No arrhythmia on EKG, CTA head and neck without acute intracranial process. During the hospital stay, she regained the ability to remember, and was discharged on 10APR2021. Subject has no recollection of her being brought to the ED or admission to ICU. She was placed on Lisinopril 10mg once daily on 13APR2021. She visited her Primary Care Provider 16APR2021, and her Lisinopril was discontinued. She started taking amlodipine 5mg once daily on 17APR2021. Today, she reports she has some residual memory issues, so this is considered ongoing. The cause of the adverse event is undetermined, further tests will include a brain MRI and kidney ultrasound. Per the PI, Dr. Thomas Campbell, MD, causality to study drug is not related. Medical records are being requested.' reason for change: New Information	Laurel Ware (b) (4) (b) (4)	22 Apr 2021 21:08:44

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

[Narrative](#)

Audit	User	Time (GMT)
User entered 'study staff was notified 20APR2021, we are attempting to gather more information at this point. this AE required a temporary medication of Lisinopril. Start dates and end dates may change.'	Laurel Ware (b) (4)	21 Apr 2021 22:28:51

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 22:28:51

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 22:28:51

US3502125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:49

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 21:08:44
User entered '0'	System	21 Apr 2021 22:28:51

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 07:56:49

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:38
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'Yes (Y)'	Josie Marshall (b) (4)	11 Sep 2020 19:49:50

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: LEVONORGESTREL, PRODUCTSYNONYM: MIRENA - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Sep 2020 19:52:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Sep 2020 19:52:43
Data point term sent to Coder	System	11 Sep 2020 19:52:13
User entered 'mirena'	Josie Marshall (b) (4)	11 Sep 2020 19:51:35

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'Yes (Y)'	Josie Marshall (b) (4)	11 Sep 2020 19:51:35

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'pregnancy prevention'	Josie Marshall (b) (4)	11 Sep 2020 19:51:35

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered '1'	Josie Marshall (b) (4)	11 Sep 2020 19:51:35

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'Other (OTHER)'	Josie Marshall (b) (4)	11 Sep 2020 19:51:35

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'iud'	Josie Marshall (b) (4)	11 Sep 2020 19:51:35

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User closed query 'Per DM CLR: Please review recorded Frequency as this is not the expected frequency for this medication. Please determine how many years would the IUD before it is replaced and update as frequency as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 05:42:31
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	19 Nov 2020 00:21:48
User entered 'other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 00:21:48
Query 'Per DM CLR: Please review recorded Frequency as this is not the expected frequency for this medication. Please determine how many years would the IUD before it is replaced and update as frequency as appropriate. Otherwise, clarify. ' answered with 'Done' (Site from DM).		19 Nov 2020 00:21:39
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	19 Nov 2020 00:21:31
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 00:21:31
User opened query 'Per DM CLR: Please review recorded Frequency as this is not the expected frequency for this medication. Please determine how many years would the IUD before it is replaced and update as frequency as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:37:02
User entered 'once daily (QD)'	Josie Marshall (b) (4) (b) (4)	11 Sep 2020 19:51:35

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'every 6 years' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 00:21:31
User entered empty.	Josie Marshall (b) (4)	11 Sep 2020 19:51:35

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'Vaginal (VAGINAL)'	Josie Marshall (b) (4)	11 Sep 2020 19:51:35

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered empty.	Josie Marshall (b) (4)	11 Sep 2020 19:51:35

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'un UNK 2016'	Josie Marshall (b) (4)	11 Sep 2020 19:51:35

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:49

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered '0'	Josie Marshall (b) (4)	11 Sep 2020 19:51:35

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'Yes (Y)'	Josie Marshall (b) (4)	11 Sep 2020 19:51:35

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered empty.	(b) (4) Josie Marshall (b) (4)	11 Sep 2020 19:51:35
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'No (N)'	Josie Marshall (b) (4)	11 Sep 2020 19:51:35

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 00:21:31
User entered '1'	System	11 Sep 2020 19:51:35

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 00:21:31
User entered '1'	System	11 Sep 2020 19:51:35

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 00:21:31
User entered '804 (804)'	System	11 Sep 2020 19:51:35

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:49

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
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)	11 Sep 2020 19:54:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 19:54:48
Data point term sent to Coder	System	11 Sep 2020 19:53:16
User entered 'multivitamin'	Josie Marshall (b) (4)	11 Sep 2020 19:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'Yes (Y)'	Josie Marshall (b) (4)	11 Sep 2020 19:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'general wellness'	Josie Marshall (b) (4)	11 Sep 2020 19:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered '1'	Josie Marshall (b) (4)	11 Sep 2020 19:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'tablet (TABLET)'	Josie Marshall (b) (4)	11 Sep 2020 19:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered empty.	(b) (4) Josie Marshall (b) (4)	11 Sep 2020 19:52:17
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'once daily (QD)'	Josie Marshall (b) (4)	11 Sep 2020 19:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered empty.	(b) (4) Josie Marshall (b) (4)	11 Sep 2020 19:52:17
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'Oral (ORAL)'	Josie Marshall (b) (4)	11 Sep 2020 19:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
	(b) (4)	
User entered empty.	Josie Marshall (b) (4)	11 Sep 2020 19:52:17
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'un UNK 2001'	Josie Marshall (b) (4)	11 Sep 2020 19:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered '0'	Josie Marshall (b) (4)	11 Sep 2020 19:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'Yes (Y)'	Josie Marshall (b) (4)	11 Sep 2020 19:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered empty.	(b) (4) Josie Marshall (b) (4)	11 Sep 2020 19:52:17
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'No (N)'	Josie Marshall (b) (4)	11 Sep 2020 19:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 19:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 19:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 19:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 19:54:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 19:54:48
Data point term sent to Coder User entered 'ibuprofen'	System Josie Marshall (b) (4)	11 Sep 2020 19:53:15 11 Sep 2020 19:52:52

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'No (N)'	Josie Marshall (b) (4)	11 Sep 2020 19:52:52

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User closed query 'Per CDM Re Query: Please review Indication and please note, there is no corresponding MH record that match the condition. Please update to record the corresponding MH as appropriate. Otherwise, clarify '(Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 04:54:19
Query 'Per CDM Re Query: Please review Indication and please note, there is no corresponding MH record that match the condition. Please update to record the corresponding MH as appropriate. Otherwise, clarify ' answered with 'Done' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 21:40:28
User opened query 'Per CDM Re Query: Please review Indication and please note, there is no corresponding MH record that match the condition. Please update to record the corresponding MH as appropriate. Otherwise, clarify '(Site from DM).	(b) (4), (b) (6)	25 Nov 2020 06:20:53
User closed query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH record that match the condition. Please update to record the corresponding MH as appropriate. Otherwise, clarify. '(Site from DM).	(b) (4), (b) (6)	25 Nov 2020 06:20:53
Query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH record that match the condition. Please update to record the corresponding MH as appropriate. Otherwise, clarify. ' answered with 'Done' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 00:22:04
User opened query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH record that match the condition. Please update to record the corresponding MH as appropriate. Otherwise, clarify. '(Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:36:34
User entered 'general aches'	Josie Marshall (b) (4) (b) (4)	11 Sep 2020 19:52:52

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered '600'	Josie Marshall (b) (4)	11 Sep 2020 19:52:52

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'mg (mg)'	Josie Marshall (b) (4)	11 Sep 2020 19:52:52

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered empty.	(b) (4) Josie Marshall (b) (4)	11 Sep 2020 19:52:52
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'as needed (PRN)'	Josie Marshall (b) (4)	11 Sep 2020 19:52:52

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered empty.	(b) (4) Josie Marshall (b) (4)	11 Sep 2020 19:52:52
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'Oral (ORAL)'	Josie Marshall (b) (4)	11 Sep 2020 19:52:52

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
	(b) (4)	
User entered empty.	Josie Marshall (b) (4)	11 Sep 2020 19:52:52
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'un UNK 2000'	Josie Marshall (b) (4)	11 Sep 2020 19:52:52

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered '0'	Josie Marshall (b) (4)	11 Sep 2020 19:52:52

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'Yes (Y)'	Josie Marshall (b) (4)	11 Sep 2020 19:52:52

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered empty.	Josie Marshall (b) (4)	11 Sep 2020 19:52:52

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'No (N)'	Josie Marshall (b) (4)	11 Sep 2020 19:52:52

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 19:52:52

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 19:52:52

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 19:52:52

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:49

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	11 Sep 2020 19:55:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 19:55:39
Data point term sent to Coder	System	11 Sep 2020 19:54:17
User entered 'tylenol'	Josie Marshall (b) (4) (b) (4)	11 Sep 2020 19:53:30

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'No (N)'	Josie Marshall (b) (4)	11 Sep 2020 19:53:30

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User closed query 'Per CDM Re Query: Please review Indication and please note, there is no corresponding MH record that match the condition. Please update to record the corresponding MH as appropriate. Otherwise, clarify' (Site from DM). Query 'Per CDM Re Query: Please review Indication and please note, there is no corresponding MH record that match the condition. Please update to record the corresponding MH as appropriate. Otherwise, clarify' answered with 'Done' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 04:54:44
User opened query 'Per CDM Re Query: Please review Indication and please note, there is no corresponding MH record that match the condition. Please update to record the corresponding MH as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 21:40:35
User closed query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH record that match the condition. Please update to record the corresponding MH as appropriate. Otherwise, clarify. (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 06:19:22
Query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH record that match the condition. Please update to record the corresponding MH as appropriate. Otherwise, clarify. (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 00:22:17
User opened query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH record that match the condition. Please update to record the corresponding MH as appropriate. Otherwise, clarify. (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:37:21
User entered 'general aches'	Josie Marshall (b) (4) (b) (4)	11 Sep 2020 19:53:30

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered '1000'	Josie Marshall (b) (4)	11 Sep 2020 19:53:30

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'mg (mg)'	Josie Marshall (b) (4)	11 Sep 2020 19:53:30

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered empty.	(b) (4) Josie Marshall (b) (4)	11 Sep 2020 19:53:30
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'as needed (PRN)'	Josie Marshall (b) (4)	11 Sep 2020 19:53:30

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered empty.	(b) (4) Josie Marshall (b) (4)	11 Sep 2020 19:53:30
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'Oral (ORAL)'	Josie Marshall (b) (4)	11 Sep 2020 19:53:30

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered empty.	(b) (4) Josie Marshall (b) (4)	11 Sep 2020 19:53:30
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
	(b) (4)	
User entered 'un UNK 2000'	Josie Marshall (b) (4)	11 Sep 2020 19:53:30
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:49

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered '0'	Josie Marshall (b) (4)	11 Sep 2020 19:53:30

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'Yes (Y)'	Josie Marshall (b) (4)	11 Sep 2020 19:53:30

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered empty.	(b) (4) Josie Marshall (b) (4)	11 Sep 2020 19:53:30
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'No (N)'	Josie Marshall (b) (4)	11 Sep 2020 19:53:30

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 19:53:30

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 19:53:30

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 19:53:30

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:56:49

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:29:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Nov 2020 11:04:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Nov 2020 11:04:57
Data point term sent to Coder	System	19 Nov 2020 00:27:40
Coding entries removed.	(b) (4), (b) (6)	19 Nov 2020 00:27:20
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Oct 2020 23:23:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Oct 2020 23:23:31
Data point term sent to Coder	System	15 Oct 2020 23:22:36
User entered 'Ibuprofen'	Patrisha Adkins (b) (4)	15 Oct 2020 23:22:29

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:56:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:29:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'No (N)'	(b) (4) Patrisha Adkins (b) (4)	15 Oct 2020 23:22:29

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:56:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:29:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE, MYALGIA are considered solicited local or systemic adverse reactions, and meet any of the following criteria: result in a visit to a healthcare provider (MAAE), lead to withdrawal from the study or study vaccination, or otherwise meet the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reactions of HEADACHE, MYALGIA did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 05:05:04
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE, MYALGIA are considered solicited local or systemic adverse reactions, and meet any of the following criteria: result in a visit to a healthcare provider (MAAE), lead to withdrawal from the study or study vaccination, or otherwise meet the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reactions of HEADACHE, MYALGIA did not meet the AE reporting criteria.' answered with 'Does not meet AE requirement' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 21:40:50

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:56:49

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE, MYALGIA are considered solicited local or systemic adverse reactions, and meet any of the following criteria: result in a visit to a healthcare provider (MAAE), lead to withdrawal from the study or study vaccination, or otherwise meet the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reactions of HEADACHE, MYALGIA did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 05:48:21
User entered 'Headache, myalgia PER DIARY' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 00:27:20
User entered 'Symptoms per diary'	Patrisha Adkins (b) (4)	15 Oct 2020 23:22:29
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:56:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:29:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered '200'	(b) (4) Patrisha Adkins (b) (4)	15 Oct 2020 23:22:29

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:56:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:29:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'mg (mg)'	Patrishia Adkins (b) (4)	15 Oct 2020 23:22:29

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:56:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:29:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered empty.	(b) (4) Patrisha Adkins (b) (4)	15 Oct 2020 23:22:29

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:56:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:29:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'once (ONCE)'	(b) (4) Patrisha Adkins (b) (4)	15 Oct 2020 23:22:29

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:56:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:29:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered empty.	(b) (4) Patrisha Adkins (b) (4)	15 Oct 2020 23:22:29

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:56:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:29:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'Oral (ORAL)'	(b) (4) Patrisha Adkins (b) (4)	15 Oct 2020 23:22:29

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:56:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:29:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered empty.	(b) (4) Patrishia Adkins (b) (4)	15 Oct 2020 23:22:29

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:56:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:29:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered '8 Oct 2020'	Patrishia Adkins (b) (4)	15 Oct 2020 23:22:29

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:56:49

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:29:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered '0'	Patrishia Adkins (b) (4)	15 Oct 2020 23:22:29

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:56:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:29:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'No (N)'	Patrishia Adkins (b) (4)	15 Oct 2020 23:22:29

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:29:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered '8 Oct 2020'	(b) (4) Patrisha Adkins (b) (4)	15 Oct 2020 23:22:29

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:56:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:29:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'Yes (Y)'	Patrishia Adkins (b) (4)	15 Oct 2020 23:22:29

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:56:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:29:48
User entered empty.	System	15 Oct 2020 23:22:29

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:56:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:29:48
User entered empty.	System	15 Oct 2020 23:22:29

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:56:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:29:48
User entered empty.	System	15 Oct 2020 23:22:29

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:49

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:50:58
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Nov 2020 00:28:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Nov 2020 00:28:50
Data point term sent to Coder Coding entries removed.	System	19 Nov 2020 00:27:39
	(b) (4), (b) (6)	19 Nov 2020 00:27:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Oct 2020 23:25:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Oct 2020 23:25:34
Data point term sent to Coder	System	15 Oct 2020 23:24:39
User entered 'Acetaminophen'	Patrishia Adkins (b) (4)	15 Oct 2020 23:23:49
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:50:58
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'No (N)'	(b) (4) Patrisha Adkins (b) (4)	15 Oct 2020 23:23:49

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:50:58
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE, MYALGIA PER DIARY are considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE, MYALGIA PER DIARY did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 12:30:56
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE, MYALGIA PER DIARY are considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE, MYALGIA PER DIARY did not meet the AE reporting criteria.' answered with 'took aceminophen for one day, no ongoing sx's and no medical attention. no ae' (Site from DM).	Suzanne Fiorillo (b) (4) (b) (4)	22 Feb 2021 21:16:09

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:49

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE, MYALGIA PER DIARY are considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE, MYALGIA PER DIARY did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 02:08:42
User entered 'Headache, myalgia PER DIARY' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 00:27:10
User entered 'Symptoms per diary'	Patrishia Adkins (b) (4)	15 Oct 2020 23:23:49
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:50:58
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered '500'	(b) (4) Patrisha Adkins (b) (4)	15 Oct 2020 23:23:49

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:50:58
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'mg (mg)'	(b) (4) Patrisha Adkins (b) (4)	15 Oct 2020 23:23:49

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:50:58
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered empty.	(b) (4) Patrisha Adkins (b) (4)	15 Oct 2020 23:23:49

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:50:58
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'once (ONCE)'	(b) (4) Patrisha Adkins (b) (4)	15 Oct 2020 23:23:49

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:50:58
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered empty.	Patrishia Adkins (b) (4)	15 Oct 2020 23:23:49

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:50:58
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'Oral (ORAL)'	(b) (4) Patrisha Adkins (b) (4)	15 Oct 2020 23:23:49

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:50:58
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered empty.	(b) (4) Patrisha Adkins (b) (4)	15 Oct 2020 23:23:49

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:50:58
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered '8 Oct 2020'	Patrishia Adkins (b) (4)	15 Oct 2020 23:23:49

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:49

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:50:58
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered '0'	Patrishia Adkins (b) (4)	15 Oct 2020 23:23:49

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:50:58
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'No (N)'	(b) (4) Patrisha Adkins (b) (4)	15 Oct 2020 23:23:49

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:50:58
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered '8 Oct 2020'	Patrishia Adkins (b) (4)	15 Oct 2020 23:23:49

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:50:58
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'Yes (Y)'	Patrishia Adkins (b) (4)	15 Oct 2020 23:23:49

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:50:58
User entered empty.	System	15 Oct 2020 23:23:49

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:50:58
User entered empty.	System	15 Oct 2020 23:23:49

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:50:58
User entered empty.	System	15 Oct 2020 23:23:49

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:49

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:19:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Nov 2020 08:19:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Nov 2020 08:19:32
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	19 Nov 2020 00:27:39 19 Nov 2020 00:26:40
User entered 'NAPROXEN' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 00:26:40
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN, PRODUCTSYNONYM: NAPROXIN [NAPROXEN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Oct 2020 05:34:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Oct 2020 05:34:26
Data point term sent to Coder	System	15 Oct 2020 23:25:39
User entered 'Naproxin'	Patrishia Adkins (b) (4)	15 Oct 2020 23:24:54
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:19:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'No (N)'	Patrishia Adkins (b) (4)	15 Oct 2020 23:24:54

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:19:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE, MYALGIA are considered solicited local or systemic adverse reactions, and meet any of the following criteria: result in a visit to a healthcare provider (MAAE), lead to withdrawal from the study or study vaccination, or otherwise meet the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reactions of HEADACHE, MYALGIA did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 05:05:26
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE, MYALGIA are considered solicited local or systemic adverse reactions, and meet any of the following criteria: result in a visit to a healthcare provider (MAAE), lead to withdrawal from the study or study vaccination, or otherwise meet the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reactions of HEADACHE, MYALGIA did not meet the AE reporting criteria.' answered with 'Does not meet AE requirement' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 21:41:11

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:49

Indication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE, MYALGIA are considered solicited local or systemic adverse reactions, and meet any of the following criteria: result in a visit to a healthcare provider (MAAE), lead to withdrawal from the study or study vaccination, or otherwise meet the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reactions of HEADACHE, MYALGIA did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 05:49:10
User entered 'Headache, myalgia PER DIARY' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 00:26:59
User entered 'Symptoms per diary'	Patrisha Adkins (b) (4)	15 Oct 2020 23:24:54

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:19:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered '220'	Patrishia Adkins (b) (4)	15 Oct 2020 23:24:54

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:19:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'mg (mg)'	Patrishia Adkins (b) (4)	15 Oct 2020 23:24:54

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:19:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered empty.	(b) (4) Patrisha Adkins (b) (4)	15 Oct 2020 23:24:54

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:19:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'once (ONCE)'	(b) (4) Patrisha Adkins (b) (4)	15 Oct 2020 23:24:54

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:19:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered empty.	(b) (4) Patrisha Adkins (b) (4)	15 Oct 2020 23:24:54

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:19:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'Oral (ORAL)'	(b) (4) Patrishia Adkins (b) (4)	15 Oct 2020 23:24:54

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:19:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered empty.	(b) (4) Patrisha Adkins (b) (4)	15 Oct 2020 23:24:54

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:49

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:19:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered '8 Oct 2020'	(b) (4) Patrisha Adkins (b) (4)	15 Oct 2020 23:24:54

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:49

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:19:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered '0'	Patrishia Adkins (b) (4)	15 Oct 2020 23:24:54

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:19:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'No (N)'	Patrishia Adkins (b) (4)	15 Oct 2020 23:24:54

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:19:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered '8 Oct 2020'	Patrishia Adkins (b) (4)	15 Oct 2020 23:24:54

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:19:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'Yes (Y)'	Patrishia Adkins (b) (4)	15 Oct 2020 23:24:54

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:19:04
User entered empty.	System	15 Oct 2020 23:24:54

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:19:04
User entered empty.	System	15 Oct 2020 23:24:54

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:19:04
User entered empty.	System	15 Oct 2020 23:24:54

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:56:18
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Nov 2020 17:53:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Nov 2020 17:53:20
Data point term sent to Coder	System	06 Nov 2020 17:52:55
User entered 'flu vaccine'	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:56:18
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:56:18
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'flu prevention'	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:56:18
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered '0.5'	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:56:18
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'mL (mL)'	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:56:18
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered empty.	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:56:18
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'once (ONCE)'	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:56:18
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered empty.	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:56:18
User signature succeeded.	Thomas Campbell (b) (4) (b) (4)	19 Mar 2021 19:43:11
User entered 'Intramuscular (INTRAMUSCULAR)'	Suzanne Fiorillo (b) (4) (b) (4)	06 Nov 2020 17:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:56:18
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered empty.	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:56:18
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered '29 Oct 2020'	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:49

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:56:18
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered '0'	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:56:18
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'No (N)'	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:56:18
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered '29 Oct 2020'	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:56:18
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:11
User entered 'No (N)'	Suzanne Fiorillo (b) (4)	06 Nov 2020 17:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:56:18
User entered empty.	System	06 Nov 2020 17:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:56:18
User entered empty.	System	06 Nov 2020 17:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:56:18
User entered empty.	System	06 Nov 2020 17:52:17

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:56:49

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Apr 2021 02:15:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 02:15:55
Data point term sent to Coder	System	22 Apr 2021 21:13:28
User entered 'lisinopril'	Laurel Ware (b) (4) (b) (4)	22 Apr 2021 21:12:56

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:56:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered 'No (N)'	(b) (4) Laurel Ware (b) (4)	22 Apr 2021 21:12:56
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:56:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered 'Transient Global Amnesia'	(b) (4) Laurel Ware (b) (4) (b) (4)	22 Apr 2021 21:12:56

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:56:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered '10'	(b) (4) Laurel Ware (b) (4)	22 Apr 2021 21:12:56
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:56:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered 'mg (mg)'	(b) (4) Laurel Ware (b) (4) (b) (4)	22 Apr 2021 21:12:56

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:56:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered empty.	(b) (4) Laurel Ware (b) (4)	22 Apr 2021 21:12:56
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:56:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered 'once daily (QD)'	(b) (4) Laurel Ware (b) (4)	22 Apr 2021 21:12:56
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:56:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered empty.	(b) (4) Laurel Ware (b) (4) (b) (4)	22 Apr 2021 21:12:56

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:56:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered 'Oral (ORAL)'	(b) (4) Laurel Ware (b) (4)	22 Apr 2021 21:12:56
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:56:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered empty.	(b) (4) Laurel Ware (b) (4) (b) (4)	22 Apr 2021 21:12:56

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:56:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered '13 Apr 2021'	(b) (4) Laurel Ware (b) (4)	22 Apr 2021 21:12:56
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:56:49

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered '0'	(b) (4) Laurel Ware (b) (4) (b) (4)	22 Apr 2021 21:12:56

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:56:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered 'No (N)'	(b) (4) Laurel Ware (b) (4)	22 Apr 2021 21:12:56
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered '16 Apr 2021'	(b) (4) Laurel Ware (b) (4)	22 Apr 2021 21:12:56
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:56:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered 'No (N)'	(b) (4) Laurel Ware (b) (4)	22 Apr 2021 21:12:56
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:56:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 21:12:56

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:56:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 21:12:56

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:56:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Apr 2021 21:12:56

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:56:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 00:07:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 00:07:58
Data point term sent to Coder	System	22 Apr 2021 21:14:29
User entered 'amlodipine'	Laurel Ware (b) (4)	22 Apr 2021 21:13:36

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:56:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered 'No (N)'	(b) (4) Laurel Ware (b) (4)	22 Apr 2021 21:13:36
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:56:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered 'Transient Global Amnesia'	(b) (4) Laurel Ware (b) (4) (b) (4)	22 Apr 2021 21:13:36

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:56:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered '5'	(b) (4) Laurel Ware (b) (4) (b) (4)	22 Apr 2021 21:13:36

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:56:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered 'mg (mg)'	(b) (4) Laurel Ware (b) (4)	22 Apr 2021 21:13:36
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:56:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
	(b) (4)	
User entered empty.	Laurel Ware (b) (4)	22 Apr 2021 21:13:36
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:56:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered 'once daily (QD)'	(b) (4) Laurel Ware (b) (4)	22 Apr 2021 21:13:36
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:56:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
	(b) (4)	
User entered empty.	Laurel Ware (b) (4)	22 Apr 2021 21:13:36
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:56:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered 'Oral (ORAL)'	(b) (4) Laurel Ware (b) (4) (b) (4)	22 Apr 2021 21:13:36

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:56:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
	(b) (4)	
User entered empty.	Laurel Ware (b) (4)	22 Apr 2021 21:13:36
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:56:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
	(b) (4)	
User entered '17 Apr 2021'	Laurel Ware (b) (4)	22 Apr 2021 21:13:36
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:56:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
	(b) (4)	
User entered '0'	Laurel Ware (b) (4)	22 Apr 2021 21:13:36
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:56:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered 'Yes (Y)'	(b) (4) Laurel Ware (b) (4)	22 Apr 2021 21:13:36
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:56:49

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

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
	(b) (4)	
User entered empty.	Laurel Ware (b) (4)	22 Apr 2021 21:13:36
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:56:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered 'No (N)'	(b) (4) Laurel Ware (b) (4)	22 Apr 2021 21:13:36
	(b) (4)	

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:56:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 21:13:36

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:56:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 21:13:36

US3502125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:56:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Apr 2021 21:13:36

US3502125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 07:56:49

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:38
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Signature has been broken.	(b) (4) Laurel Ware (b) (4)	22 Apr 2021 21:10:09
User entered 'Yes (Y)' reason for change: New Information	(b) (4) Laurel Ware (b) (4)	22 Apr 2021 21:10:09
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:45:22
User entered 'No (N)'	(b) (4) Suzanne Fiorillo (b) (4)	08 Feb 2021 21:31:24
	(b) (4)	

US3502125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:56:49

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered '09 Apr 2021'	(b) (4) Laurel Ware (b) (4)	22 Apr 2021 21:10:54
	(b) (4)	

US3502125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:56:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered 'EKG'	(b) (4) Laurel Ware (b) (4)	22 Apr 2021 21:10:54
	(b) (4)	

US3502125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:56:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered 'Adverse Event (AE)'	(b) (4) Laurel Ware (b) (4)	22 Apr 2021 21:10:54
	(b) (4)	

US3502125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:56:49

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered empty.	(b) (4) Laurel Ware (b) (4)	22 Apr 2021 21:10:54
	(b) (4)	

US3502125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 07:56:49

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
	(b) (4)	
User entered '09 Apr 2021'	Laurel Ware (b) (4)	22 Apr 2021 21:11:33
	(b) (4)	

US3502125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 07:56:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered 'CTA head and neck'	(b) (4) Laurel Ware (b) (4) (b) (4)	22 Apr 2021 21:11:33

US3502125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 07:56:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered 'Adverse Event (AE)'	(b) (4) Laurel Ware (b) (4)	22 Apr 2021 21:11:33
	(b) (4)	

US3502125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 07:56:49

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
	(b) (4)	
User entered empty.	Laurel Ware (b) (4)	22 Apr 2021 21:11:33
	(b) (4)	

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'USA-US080-2021-MRNA-1273-P301000001'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'Yes (Y)'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

Death

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'No (N)'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'No (N)'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'Yes (Y)'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'No (N)'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'No (N)'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'No (N)'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'Thomas'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'Campbell'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'CO'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 11:41:59
User entered 'US'	System	22 Apr 2021 13:33:05

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Apr 2021 11:40:45
User entered '1'	System	22 Apr 2021 13:33:05

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'USA-US080-2021-MRNA-1273-P301000001'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'Yes (Y)'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

Death

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'No (N)'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'No (N)'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'Yes (Y)'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'No (N)'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'No (N)'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'No (N)'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'Thomas'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'Campbell'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'CO'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 11:41:59
User entered 'US'	System	22 Apr 2021 13:33:05

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Apr 2021 11:40:45
User entered '1'	System	22 Apr 2021 13:33:05

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 07:56:49

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered '22/Apr/2021 06:33'	(b) (4) System	22 Apr 2021 13:33:05

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 07:56:49

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.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 11:41:59
User entered '1'		22 Apr 2021 13:33:05

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'USA-US080-2021-MRNA-1273-P301000001'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'Yes (Y)'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

Death

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'No (N)'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'No (N)'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'Yes (Y)'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'No (N)'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'No (N)'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'No (N)'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'Thomas'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'Campbell'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:32:55
User entered 'CO'	System	22 Apr 2021 13:32:36

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 11:41:59
User entered 'US'	System	22 Apr 2021 13:33:05

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Apr 2021 11:40:45
User entered '1'	System	22 Apr 2021 13:33:05

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 07:56:49

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
User entered '23/Apr/2021 07:40'	(b) (4) System	23 Apr 2021 11:40:45

US3502125

Folder: SAE USA-US080-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 07:56:49

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.	Thomas Campbell (b) (4)	28 Apr 2021 10:49:04
Reviewed for Safety.	(b) (4)	23 Apr 2021 11:41:59
User entered '1'	(b) (4), (b) (6)	23 Apr 2021 11:40:45