

US3492228 (Prod: UIC Project WISH CRS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:53:02

All time stamps listed in this document are displayed in GMT

US3492228

Form: Participant Creation

Data signed: (b) (4) 15 Feb 2021 04:14:36

Generated On: 11 Aug 2021 22:53:02

[Participant ID](#)

US3492228

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

US3492228

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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

US3492228

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 04:14:37

Generated On: 11 Aug 2021 22:53:02

Date of Birth (MMM yyyy)	(b) (6) 1989
Age	30
Age Units	YEARS
Age (Derived)	30
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 04:14:37

Generated On: 11 Aug 2021 22:53:02

Date of Informed Consent (*dd MMM yyyy*) 22 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

US3492228

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 04:14:37

Generated On: 11 Aug 2021 22:53:02

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 04:14:58

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Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 04:14:37

Generated On: 11 Aug 2021 22:53:02

Condition	POLYCYSTIC OVARY SYNDROME
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 04:14:37

Generated On: 11 Aug 2021 22:53:02

Condition	ACNE
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3492228

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 04:14:37

Generated On: 11 Aug 2021 22:53:02

Condition	MENSTRUAL HEADACHES
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

Were vital signs assessed? Yes
No

Date of assessment (*dd MMM yyyy*) 22 SEP 2020

Time of assessment (*00:00-23:59*) 09:52 (24 HR)

Vital Signs Date and Time (derived) 22 SEP 2020 09:52

Height (*xxx.x*) 161 cm

Weight (*xxx.x*) 57 kg

BMI (*xxx.x*) 21.98989 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) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

22 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) 15 Feb 2021 04:14:37

Generated On: 11 Aug 2021 22:53:02

Date of assessment (*dd MMM yyyy*) 22 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) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 22 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) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

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 (b) (6)

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

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)	True
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 22 SEP 2020

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

Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

What was the date of randomization? (dd MMM yyyy) 22 SEP 2020

What was the participant's randomization number? 115170

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) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

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>)	22 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:52 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 09:52
Temperature (<i>xxx.x</i>)	36.4 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (<i>xxx</i>)	60 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	81 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

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>)	22 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:50 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 10:50
Temperature (<i>xxx.x</i>)	35.3 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (<i>xxx</i>)	69 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

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) 26 Mar 2021 01:51:21

Generated On: 11 Aug 2021 22:53:02

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) _____

US3492228

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

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) 22 SEP 2020

What was the treatment time? (00:00-23:59) 10:45 (24 HR)

Treatment Date and Time (derived) 22 SEP 2020 10:45

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	22 SEP 2020
Collection time (<i>00:00-23:59</i>)	10:08 (24 HR)
Collection date and time (derived)	22 SEP 2020 10:08

US3492228

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

Collection date (<i>dd MMM yyyy</i>)			22 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	10:00	22 SEP 2020 10:00
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

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: 11 Aug 2021 22:53:02

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 95.6 °F

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

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

PC Time Stamp 22 SEP 2020 11:14

PC Open Date & Time 22 SEP 2020 11:05

PC Close Date & Time 22 SEP 2020 13:35

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

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 96.0 °F

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

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

PC Time Stamp 22 SEP 2020 17:51
PC Open Date & Time 22 SEP 2020 14:30
PC Close Date & Time 23 SEP 2020 11:59

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:53:02

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	96.1 °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	23 SEP 2020 21:07
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:53:02

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	95.7 °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	24 SEP 2020 23:01
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

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

PC Time Stamp	25 SEP 2020 17:57
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

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

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

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

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

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

PC Time Stamp 26 SEP 2020 12:28

PC Open Date & Time 26 SEP 2020 12:00

PC Close Date & Time 27 SEP 2020 11:59

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:53:02

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	97.3 °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	27 SEP 2020 15:48
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:53:02

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	96.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	28 SEP 2020 21:51
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

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

22 SEP 2020 11:14

PC Open Date & Time

22 SEP 2020 11:05

PC Close Date & Time

22 SEP 2020 13:35

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

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

22 SEP 2020 17:51

PC Open Date & Time

22 SEP 2020 14:30

PC Close Date & Time

23 SEP 2020 11:59

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:53:02

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	23 SEP 2020 14:26
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:53:02

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	24 SEP 2020 20:17
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:53:02

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

25 SEP 2020 17:57

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:53:02

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

26 SEP 2020 12:25

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:53:02

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

27 SEP 2020 15:49

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 7

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

None

Please select one response below

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

None

Please select one response below

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

28 SEP 2020 21:51

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

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

No

Yes

PC Time stamp	22 SEP 2020 11:15
PC Open Date & Time	22 SEP 2020 11:05
PC Close Date & Time	22 SEP 2020 13:35

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

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

No

Yes

PC Time stamp	22 SEP 2020 17:52
PC Open Date & Time	22 SEP 2020 14:30
PC Close Date & Time	23 SEP 2020 11:59

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:02

	Yes <input type="checkbox"/>
PC Time stamp	23 SEP 2020 14:26
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:02

	Yes <input type="checkbox"/>
PC Time stamp	24 SEP 2020 20:18
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:02

	Yes <input type="checkbox"/>
PC Time stamp	25 SEP 2020 17:57
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:02

	Yes <input type="checkbox"/>
PC Time stamp	26 SEP 2020 12:25
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:02

	Yes <input type="checkbox"/>
PC Time stamp	27 SEP 2020 15:49
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:02

	Yes <input type="checkbox"/>
PC Time stamp	28 SEP 2020 21:51
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3492228

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:14:37

Generated On: 11 Aug 2021 22:53:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 29 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3492228

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:14:37

Generated On: 11 Aug 2021 22:53:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3492228

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:14:37

Generated On: 11 Aug 2021 22:53:02

Was Contact Attempted?

Yes

No

Date of Contact or Contact Attempt (*dd MMM yyyy*)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made

Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3492228

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:14:37

Generated On: 11 Aug 2021 22:53:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3492228

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:14:37

Generated On: 11 Aug 2021 22:53:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 13 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3492228

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:14:37

Generated On: 11 Aug 2021 22:53:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3492228

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

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>)	22 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:22 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 11:22
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	EAR
Pulse (<i>xxx</i>)	71 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	96 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

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>)	22 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	12:13 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 12:13
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	TYMPANIC
Pulse (<i>xxx</i>)	63 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3492228

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

22 OCT 2020

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

US3492228

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 22 OCT 2020

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

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

US3492228

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

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) 22 OCT 2020

What was the treatment time? (00:00-23:59) 12:09 (24 HR)

Treatment Date and Time (derived) 22 OCT 2020 12:09

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

US3492228

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 22 OCT 2020

Collection time (*00:00-23:59*) 11:40 (24 HR)

Collection date and time (derived) 22 OCT 2020 11:40

US3492228

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

Collection date (<i>dd MMM yyyy</i>)			22 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	11:46	22 OCT 2020 11:46
Nasopharyngeal Swab 2	No		

US3492228

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

PC Time Stamp 22 OCT 2020 12:38

PC Open Date & Time 22 OCT 2020 12:29

PC Close Date & Time 22 OCT 2020 14:59

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

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 97.3 °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 22 OCT 2020 19:13
PC Open Date & Time 22 OCT 2020 15:54
PC Close Date & Time 23 OCT 2020 11:59

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:53:02

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	97.1 °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	23 OCT 2020 20:30
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:53:02

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	97.7 °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	24 OCT 2020 16:29
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:53:02

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	95.5 °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	25 OCT 2020 18:35
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:53:02

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	97.2 °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	27 OCT 2020 09:35
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:53:02

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	96.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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	27 OCT 2020 22:52
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.8 °F

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

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

PC Time Stamp 28 OCT 2020 19:24

PC Open Date & Time 28 OCT 2020 12:00

PC Close Date & Time 29 OCT 2020 11:59

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

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	22 OCT 2020 12:38
PC Open Date & Time	22 OCT 2020 12:29
PC Close Date & Time	22 OCT 2020 14:59

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

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	22 OCT 2020 19:13
PC Open Date & Time	22 OCT 2020 15:54
PC Close Date & Time	23 OCT 2020 11:59

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:53:02

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	23 OCT 2020 20:30
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:53:02

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

24 OCT 2020 16:22

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:53:02

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	25 OCT 2020 18:35
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:53:02

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	27 OCT 2020 09:35
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:53:02

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

27 OCT 2020 22:52

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:53:02

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

28 OCT 2020 19:24

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

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

No

Yes

PC Time stamp	22 OCT 2020 12:38
PC Open Date & Time	22 OCT 2020 12:29
PC Close Date & Time	22 OCT 2020 14:59

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

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

No

Yes

PC Time stamp	22 OCT 2020 19:14
PC Open Date & Time	22 OCT 2020 15:54
PC Close Date & Time	23 OCT 2020 11:59

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:02

	Yes <input type="checkbox"/>
PC Time stamp	23 OCT 2020 20:30
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:02

	Yes <input type="checkbox"/>
PC Time stamp	24 OCT 2020 16:22
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:02

	Yes <input type="checkbox"/>
PC Time stamp	25 OCT 2020 18:35
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:02

	Yes <input type="checkbox"/>
PC Time stamp	27 OCT 2020 09:35
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:02

	Yes <input type="checkbox"/>
PC Time stamp	27 OCT 2020 22:53
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:02

	Yes <input type="checkbox"/>
PC Time stamp	28 OCT 2020 19:25
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3492228

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:14:37

Generated On: 11 Aug 2021 22:53:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 30 OCT 2020

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

Comments 3 CALL ATTEMPTS MADE, NO
CONTACT WITH PARTICIPANT.
If Contact Not Made, please provide Comments PROXY CONTACT
INFORMATION CONTAINED A
WRONG PHONE NUMBER.

US3492228

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:14:37

Generated On: 11 Aug 2021 22:53:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3492228

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:14:37

Generated On: 11 Aug 2021 22:53:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 5 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3492228

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:14:37

Generated On: 11 Aug 2021 22:53:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3492228

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:14:37

Generated On: 11 Aug 2021 22:53:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 13 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3492228

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:14:37

Generated On: 11 Aug 2021 22:53:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3492228

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3492228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	17 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	13:20 (24 HR)
Vital Signs Date and Time (derived)	17 NOV 2020 13:20
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	TYMPANIC
Pulse (<i>xxx</i>)	69 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3492228

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

17 NOV 2020

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

US3492228

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	17 NOV 2020
Collection time (<i>00:00-23:59</i>)	13:35 (24 HR)
Collection date and time (derived)	17 NOV 2020 13:35

US3492228

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:14:58

Generated On: 11 Aug 2021 22:53:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 61

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

No

Yes

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

No

Yes

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

Date and time of submission 22 NOV 2020 00:03:30

Patient Cloud Open Date & Time 19 NOV 2020 00:01

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 68

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

No

Yes

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

No

Yes

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

Date and time of submission	28 NOV 2020 21:29:43
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission 03 DEC 2020 10:26:42

Patient Cloud Open Date & Time 03 DEC 2020 00:01

Patient Cloud Close Date & Time 07 DEC 2020 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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 <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 DEC 2020 12:24:19
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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 19 DEC 2020 09:12:30

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

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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	26 DEC 2020 12:03:47
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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 31 DEC 2020 07:22:33

Patient Cloud Open Date & Time 31 DEC 2020 00:01

Patient Cloud Close Date & Time 04 JAN 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 JAN 2021 12:09:13
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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	14 JAN 2021 07:51:44
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 124

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

No

Yes

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

No

Yes

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

Date and time of submission 23 JAN 2021 12:25:19

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

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 131

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

No

Yes

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

No

Yes

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

Date and time of submission 28 JAN 2021 09:07:05

Patient Cloud Open Date & Time 28 JAN 2021 00:01

Patient Cloud Close Date & Time 01 FEB 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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 07 FEB 2021 18:00:36

Patient Cloud Open Date & Time 04 FEB 2021 00:01

Patient Cloud Close Date & Time 08 FEB 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 19:14:26
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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 21 FEB 2021 18:30:00

Patient Cloud Open Date & Time 18 FEB 2021 00:01

Patient Cloud Close Date & Time 22 FEB 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 159

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

No

Yes

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

No

Yes

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

Date and time of submission 25 FEB 2021 10:25:16

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

Patient Cloud Close Date & Time 01 MAR 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 166

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

No

Yes

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

No

Yes

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

Date and time of submission

06 MAR 2021 14:42:20

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 173

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

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

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

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 Yes

Date and time of submission 11 MAR 2021 06:47:17

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

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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	19 MAR 2021 19:06:59
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	27 MAR 2021 12:11:13
Patient Cloud Open Date & Time	25 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 194

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

No

Yes

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

No

Yes

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

Date and time of submission	01 APR 2021 11:34:30
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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	08 APR 2021 10:11:24
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 APR 2021 13:07:52
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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	24 APR 2021 12:00:32
Patient Cloud Open Date & Time	22 APR 2021 00:01
Patient Cloud Close Date & Time	26 APR 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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 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 APR 2021 22:53:15
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 229

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 236

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 299

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

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

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

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

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

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

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

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

Patient Cloud Open Date & Time	05 AUG 2021 00:01
Patient Cloud Close Date & Time	09 AUG 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

Patient Cloud Open Date & Time	12 AUG 2021 00:01
Patient Cloud Close Date & Time	16 AUG 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission	
Patient Cloud Open Date & Time	19 AUG 2021 00:01
Patient Cloud Close Date & Time	23 AUG 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission	
Patient Cloud Open Date & Time	02 SEP 2021 00:01
Patient Cloud Close Date & Time	06 SEP 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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°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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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°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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#) 11 OCT 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

Patient Cloud Open Date & Time	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

Patient Cloud Open Date & Time	21 OCT 2021 00:01
Patient Cloud Close Date & Time	25 OCT 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

Patient Cloud Open Date & Time	02 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

Patient Cloud Open Date & Time	09 DEC 2021 00:01
Patient Cloud Close Date & Time	13 DEC 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#) 27 DEC 2021 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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°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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

Patient Cloud Open Date & Time	03 FEB 2022 00:01
Patient Cloud Close Date & Time	07 FEB 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission	
Patient Cloud Open Date & Time	10 FEB 2022 00:01
Patient Cloud Close Date & Time	14 FEB 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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°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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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°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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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°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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

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

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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°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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

Patient Cloud Open Date & Time	11 AUG 2022 00:01
Patient Cloud Close Date & Time	15 AUG 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

Patient Cloud Open Date & Time	25 AUG 2022 00:01
Patient Cloud Close Date & Time	29 AUG 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

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

[Patient Cloud Close Date & Time](#) 05 SEP 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 OCT 2022 00:01
Patient Cloud Close Date & Time	24 OCT 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

[Patient Cloud Close Date & Time](#)

21 NOV 2022 23:59

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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

[Patient Cloud Close Date & Time](#)

28 NOV 2022 23:59

US3492228

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:53:02

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		06 MAR 2021 14:42:46

US3492228

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:14:37

Generated On: 11 Aug 2021 22:53:02

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3492228

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:14:37

Generated On: 11 Aug 2021 22:53:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3492228

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:14:37

Generated On: 11 Aug 2021 22:53:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 22 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3492228

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:14:37

Generated On: 11 Aug 2021 22:53:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3492228

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:51:21

Generated On: 11 Aug 2021 22:53:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 17 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3492228

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:51:21

Generated On: 11 Aug 2021 22:53:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3492228

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:51:21

Generated On: 11 Aug 2021 22:53:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 18 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3492228

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:51:21

Generated On: 11 Aug 2021 22:53:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3492228

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 30 Apr 2021 21:45:22

Generated On: 11 Aug 2021 22:53:02

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 27 APR 2021

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

Folder OID VISIT4

US3492228

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Apr 2021 21:45:22

Generated On: 11 Aug 2021 22:53:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	27 APR 2021
Time of assessment (<i>00:00-23:59</i>)	09:02 (24 HR)
Vital Signs Date and Time (derived)	27 APR 2021 09:02
Temperature (<i>xxx.x</i>)	96.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
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>)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3492228

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Apr 2021 21:45:22

Generated On: 11 Aug 2021 22:53:02

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

27 APR 2021

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

US3492228

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Apr 2021 21:45:22

Generated On: 11 Aug 2021 22:53:02

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 27 APR 2021

Collection time (*00:00-23:59*) 09:19 (24 HR)

Collection date and time (derived) 27 APR 2021 09:19

US3492228

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 30 Apr 2021 21:45:22

Generated On: 11 Aug 2021 22:53:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3492228

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

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 _____

US3492228

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3492228

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:53:02

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"/>

US3492228

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:53:02

Generate Next COVID-19 Assessment

Yes

No

US3492228

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

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:14:36

Generated On: 11 Aug 2021 22:53:02

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 26 JAN 2021

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

Folder OID UNBLND_DECIDE

US3492228

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

Form: Unblinding

Data signed: (b) (4) 26 Mar 2021 01:51:21

Generated On: 11 Aug 2021 22:53:02

Date of updated informed consent (<i>dd MMM yyyy</i>)	26 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	26 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3492228

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 04:14:36

Generated On: 11 Aug 2021 22:53:02

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

US3492228

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 04:14:36

Generated On: 11 Aug 2021 22:53:02

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 JAN 2021
Time of assessment (00:00-23:59)	11:19 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 11:19
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3492228

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 04:14:36

Generated On: 11 Aug 2021 22:53:02

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 JAN 2021
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 12:00
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3492228

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

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:14:36

Generated On: 11 Aug 2021 22:53:02

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

26 JAN 2021

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

US3492228

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

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 04:14:36

Generated On: 11 Aug 2021 22:53:02

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 26 JAN 2021

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

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

US3492228

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

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 04:14:36

Generated On: 11 Aug 2021 22:53:02

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

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

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

What was the treatment date? (dd MMM yyyy) 26 JAN 2021

What was the treatment time? (00:00-23:59) 11:52 (24 HR)

Treatment Date and Time (derived) 26 JAN 2021 11:52

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

What was the frequency of the study treatment dosing? ONCE

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

US3492228

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:14:36

Generated On: 11 Aug 2021 22:53:02

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 26 JAN 2021

Collection time (*00:00-23:59*) 11:08 (24 HR)

Collection date and time (derived) 26 JAN 2021 11:08

US3492228

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 15 Feb 2021 04:14:36

Generated On: 11 Aug 2021 22:53:02

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 26 JAN 2021

Collection time (*00:00 - 23:59*) 11:15

Collection Date and Time (derived) 26 JAN 2021 11:15

US3492228

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

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:14:36

Generated On: 11 Aug 2021 22:53:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3492228

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:14:37

Generated On: 11 Aug 2021 22:53:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 2 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3492228

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:14:37

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 01:51:21

Generated On: 11 Aug 2021 22:53:02

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 24 FEB 2021

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

Folder OID OLD29

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 01:51:21

Generated On: 11 Aug 2021 22:53:02

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>)	24 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	09:01 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 09:01
Temperature (<i>xxx.x</i>)	36.4 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (<i>xxx</i>)	66 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Mar 2021 01:51:21

Generated On: 11 Aug 2021 22:53:02

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>)	24 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	10:06 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 10:06
Temperature (<i>xxx.x</i>)	36.4 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TMPANIC
Pulse (<i>xxx</i>)	64 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3492228

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 01:51:21

Generated On: 11 Aug 2021 22:53:02

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

24 FEB 2021

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

US3492228

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 26 Mar 2021 01:51:21

Generated On: 11 Aug 2021 22:53:02

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 24 FEB 2021

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

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

US3492228

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 01:51:21

Generated On: 11 Aug 2021 22:53:02

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

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

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

What was the treatment date? (dd MMM yyyy) 24 FEB 2021

What was the treatment time? (00:00-23:59) 10:05 (24 HR)

Treatment Date and Time (derived) 24 FEB 2021 10:05

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

What was the frequency of the study treatment dosing? ONCE

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

US3492228

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:51:21

Generated On: 11 Aug 2021 22:53:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3492228

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:51:21

Generated On: 11 Aug 2021 22:53:02

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3492228

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:51:21

Generated On: 11 Aug 2021 22:53:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3492228

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 16:31:50

Generated On: 11 Aug 2021 22:53:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3492228

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 16:31:50

Generated On: 11 Aug 2021 22:53:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	1 APR 2021
Time of assessment (<i>00:00-23:59</i>)	11:11 (24 HR)
Vital Signs Date and Time (derived)	1 APR 2021 11:11
Temperature (<i>xxx.x</i>)	97.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (<i>xxx</i>)	59 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492228

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 16:31:50

Generated On: 11 Aug 2021 22:53:02

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

1 APR 2021

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

US3492228

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 16:31:50

Generated On: 11 Aug 2021 22:53:02

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	1 APR 2021
Collection time (<i>00:00-23:59</i>)	11:30 (24 HR)
Collection date and time (derived)	1 APR 2021 11:30

US3492228

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Feb 2021 04:14:36

Generated On: 11 Aug 2021 22:53:02

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Feb 2021 04:14:36

Generated On: 11 Aug 2021 22:53:02

AEID USA-US101-2020-MRNA-1273-P30
1000011

Adverse event ABNORMAL VAGINAL
BLEEDING

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) 22 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 15 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

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

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes
No
Unknown

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Feb 2021 04:14:36

Generated On: 11 Aug 2021 22:53:02

Number of Days in ICU _____

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product
Withdrawn
Not Applicable

Other action taken (check all that apply)

None True

Concomitant Medication False

Concomitant Procedure False

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with
Sequelae
Recovering/Resolving
Unknown

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

Narrative _____

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Feb 2021 04:14:36

Generated On: 11 Aug 2021 22:53:02

PARTICIPANT REPORTED
ABNORMAL VAGINAL
BLEEDING THAT OCCURED
22NOV2020, 12DEC2020,
15DEC2020. SHE REPORTED
THAT THE BLOOD SEEMS OLD
AND IS BROWN IN COLOR, AND
THAT IT HURTS DURING SEX.

Serious Adverse Event Derived (CSA Programming Field Only)	0
--	---

Medically Attended AE Derived (CSA Programming Field Only)	0
--	---

Admitted to ICU Derived (CSA Programming Field Only)	
--	--

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Feb 2021 04:14:36

Generated On: 11 Aug 2021 22:53:02

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

Yes

No

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

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 16:31:50

Generated On: 11 Aug 2021 22:53:02

Name of Medication METFORMIN

Prophylaxis Yes
No

Indication INSULIN RESISTANCE,
SECONDARY TO POLYCYSTIC
OVARY SYNDROME

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

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EAB) (1725)

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US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 16:31:50

Generated On: 11 Aug 2021 22:53:02

	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)	01 JAN 2018
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input checked="" type="radio"/>

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 16:31:50

Generated On: 11 Aug 2021 22:53:02

Name of Medication IBUPROFEN

Prophylaxis Yes
No

Indication HEADACHE

Dose per administration 400

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 16:31:50

Generated On: 11 Aug 2021 22:53:02

	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*) 26 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 26 SEP 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

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 16:31:50

Generated On: 11 Aug 2021 22:53:02

Name of Medication IBUPROFEN

Prophylaxis Yes
No

Indication HEADACHE

Dose per administration 400

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 16:31:50

Generated On: 11 Aug 2021 22:53:02

	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 (<i>dd MMM yyyy</i>)	27 OCT 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date (<i>dd MMM yyyy</i>)	27 OCT 2020
Was this medication taken for solicited event?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="checkbox"/>

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 16:31:50

Generated On: 11 Aug 2021 22:53:02

Name of Medication ISOTRETINOIN

Prophylaxis Yes
No

Indication ACNE

Dose per administration 20

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 16:31:50

Generated On: 11 Aug 2021 22:53:02

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*) 01 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 1 DEC 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 2

Interval Dosage Definition (derived) 802
803
804

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 16:31:50

Generated On: 11 Aug 2021 22:53:02

Name of Medication COPPER NON HORMONAL
INTRAUTERINE DEVICE

Prophylaxis Yes
No

Indication PREGNANCY PROPHYLAXIS

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify INTRAUTERINE DEVICE, NO
DOSE UNIT AS NON-DRUG
CONTAINING

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 ONCE IN PLACE FOR MULTIPLE
YEARS

Route of administration Oral
Topical

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 16:31:50

Generated On: 11 Aug 2021 22:53:02

	Subcutaneous	<input type="radio"/>
	Transdermal	<input type="radio"/>
	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>

If route of administration is Other, specify INTRAUTERINE

Start date (*dd MMM yyyy*) UN UNK 2017

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 4 FEB 2021

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

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 16:31:50

Generated On: 11 Aug 2021 22:53:02

Name of Medication PRENATAL VITAMIN

Prophylaxis Yes
No

Indication VITAMIN SUPPLEMENT

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 16:31:50

Generated On: 11 Aug 2021 22:53:02

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 MAR 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

US3492228

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Mar 2021 01:51:21

Generated On: 11 Aug 2021 22:53:02

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:53:02

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

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 15 Feb 2021 04:14:36

Generated On: 11 Aug 2021 22:53:02

SAEID	USA-US101-2020-MRNA-1273-P30 1000011
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 15 Feb 2021 04:14:36

Generated On: 11 Aug 2021 22:53:02

SAEID	USA-US101-2020-MRNA-1273-P30 1000011
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	16/DEC/2020 14:20
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 15 Feb 2021 04:14:36

Generated On: 11 Aug 2021 22:53:02

SAEID	USA-US101-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	17/DEC/2020 16:50
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

US3492228 (Prod: UIC Project WISH CRS)

US3492228

Form: Participant Creation

Generated On: 11 Aug 2021 22:53:02

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'US3492228'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Sep 2020 14:35:53

US3492228

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:18:03

US3492228

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '22 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Sep 2020 14:35:54

US3492228

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

[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 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:18:03

US3492228

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered 'SCRN'	System	22 Sep 2020 15:18:03

US3492228

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:02

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered (b) (6) 1989'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Sep 2020 14:35:55

US3492228

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:02

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '30'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:18:17

US3492228

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:02

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered 'YEARS'	System	22 Sep 2020 15:18:17

US3492228

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:02

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered '30'	System	22 Sep 2020 15:18:38

US3492228

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:02

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:18:17

US3492228

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:02

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:18:17

US3492228

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:02

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '1'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:18:17

US3492228

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:02

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:18:17

US3492228

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:02

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:18:17

US3492228

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:02

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:18:17

US3492228

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:02

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:18:17

US3492228

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:02

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:18:17

US3492228

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:02

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:18:17

US3492228

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:02

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:18:17

US3492228

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:02

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:18:17

US3492228

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:02

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:18:38

US3492228

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered 'Sep 2020'	System	22 Sep 2020 15:18:38

US3492228

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered '2020'	System	22 Sep 2020 15:18:38

US3492228

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:02

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:18:38

US3492228

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:18:38

US3492228

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:02

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:18:38

US3492228

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:02

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:18:38

US3492228

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:02

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:18:38

US3492228

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:02

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Sep 2020 14:35:54

US3492228

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:02

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered '1'	System	22 Sep 2020 15:18:44

US3492228

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:18:44

US3492228

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:53:02

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:37:54
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 15:18:58

US3492228

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User coded data point as SOC: Reproductive system and breast disorders, HLG: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Polycystic ovaries, LLT: Polycystic ovarian syndrome - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 20:40:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 20:40:36
Data point term sent to Coder	System	11 Nov 2020 20:39:35
User entered 'Polycystic Ovary syndrome'	(b) (4), (b) (6)	11 Nov 2020 20:38:39

US3492228

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'UN UNK 2005'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:38:39

US3492228

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:38:39

US3492228

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:38:39

US3492228

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:38:39

US3492228

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:38:39

US3492228

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered 'Jan 2005'	System	11 Nov 2020 20:38:39

US3492228

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered '2005'	System	11 Nov 2020 20:38:39

US3492228

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered empty.	System	11 Nov 2020 20:38:39

US3492228

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered empty.	System	11 Nov 2020 20:38:39

US3492228

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Acnes, PT: Acne, LLT: Acne - version MedDRA\\23.0.	Coder Import (b) (4)	15 Nov 2020 17:37:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Nov 2020 17:37:45
Data point term sent to Coder	System	15 Nov 2020 17:37:15
User entered 'Acne'	Andrea Wendrow (b) (4)	15 Nov 2020 17:36:32

US3492228

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered 'UN UNK 2005'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 17:36:32

US3492228

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 17:36:32

US3492228

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 17:36:32

US3492228

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 17:36:32

US3492228

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 17:36:32

US3492228

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered 'Jan 2005'	System	15 Nov 2020 17:36:32

US3492228

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered '2005'	System	15 Nov 2020 17:36:32

US3492228

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered empty.	System	15 Nov 2020 17:36:32

US3492228

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered empty.	System	15 Nov 2020 17:36:32

US3492228

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 13:04:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 13:04:41
Data point term sent to Coder	System	15 Nov 2020 17:37:22
User entered 'Menstrual headaches'	Andrea Wendrow (b) (4)	15 Nov 2020 17:37:02

US3492228

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered 'UN UNK 2005'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 17:37:02

US3492228

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 17:37:02

US3492228

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 17:37:02

US3492228

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 17:37:02

US3492228

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 17:37:02

US3492228

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered 'Jan 2005'	System	15 Nov 2020 17:37:02

US3492228

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered '2005'	System	15 Nov 2020 17:37:02

US3492228

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered empty.	System	15 Nov 2020 17:37:02

US3492228

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered empty.	System	15 Nov 2020 17:37:02

US3492228

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:20:45

US3492228

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:20:45

US3492228

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '09:52'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:20:45

US3492228

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered '22 Sep 2020 09:52'	System	22 Sep 2020 15:20:45

US3492228

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '161' cm	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:20:45
DataPoint set to visible.	System	22 Sep 2020 15:18:44

US3492228

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '57' kg	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:20:45
DataPoint set to visible.	System	22 Sep 2020 15:18:44

US3492228

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered '21.98989'	System	22 Sep 2020 15:20:45
DataPoint set to visible.	System	22 Sep 2020 15:18:44

US3492228

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered 'kg/m2'	System	22 Sep 2020 15:20:45
DataPoint set to visible.	System	22 Sep 2020 15:18:44

US3492228

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:20:45

US3492228

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:20:45

US3492228

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:20:45

US3492228

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:20:45

US3492228

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered 'bpm'	System	22 Sep 2020 15:20:45

US3492228

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:20:45

US3492228

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered 'breaths/min'	System	22 Sep 2020 15:20:45

US3492228

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:20:45

US3492228

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered 'mmHg'	System	22 Sep 2020 15:20:45

US3492228

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:20:45

US3492228

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered 'mmHg'	System	22 Sep 2020 15:20:45

US3492228

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33

US3492228

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33

US3492228

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:20:55

US3492228

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:20:55

US3492228

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:53:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:21:20

US3492228

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:53:02

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User closed query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	(b) (4)	22 Sep 2020 15:24:19
User opened query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	System	22 Sep 2020 15:22:57
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 15:22:57
User closed query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	System	22 Sep 2020 15:22:28
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 15:22:28
User opened query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	System	22 Sep 2020 15:21:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 15:21:20

US3492228

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:53:02

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User closed query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	(b) (4)	22 Sep 2020 15:22:57
User opened query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	22 Sep 2020 15:22:28
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 15:21:20

US3492228

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:53:02

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:22:57
User entered 'copper IUD' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 15:22:14
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 15:21:20

US3492228

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:21:20

US3492228

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:53:02

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:21:20

US3492228

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:21:20

US3492228

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:53:02

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '0' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:24:19
User entered '1'	(b) (4), (b) (6)	22 Sep 2020 15:21:20

US3492228

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:25:05

US3492228

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:25:05

US3492228

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:25:05

US3492228

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:25:05

US3492228

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:25:05

US3492228

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:25:05

US3492228

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:25:05

US3492228

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered empty.	System	22 Sep 2020 15:25:05

US3492228

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:02

[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 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:25:52

US3492228

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:02

[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 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:25:52

US3492228

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:02

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 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:25:52

US3492228

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:02

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 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:25:52

US3492228

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:02

[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 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:25:52

US3492228

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:02

[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 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:25:52

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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 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:25:52

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Folder: Screening

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[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 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:25:52

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[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 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:25:52

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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 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:25:52

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Folder: Screening

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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 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:25:52

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Folder: Screening

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:25:52

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered (b) (6)	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:25:52

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:25:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:02

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:25:52

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Folder: Screening

Form: Risk of Exposure

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[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 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:25:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:02

[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 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '1'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:25:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:02

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 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:25:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:25:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:02

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:25:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:02

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:25:52

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:26:11

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:26:11

US3492228

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:26:11

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered 'VISIT1'	System	22 Sep 2020 15:26:11

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '22 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Sep 2020 14:56:19

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:02

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '115170'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Sep 2020 14:56:19

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Sep 2020 14:56:19

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:26:47

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:26:47

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:26:47

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:02

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:26:47

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:02

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:26:47

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:02

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:26:47
DataPoint set to visible.	System	22 Sep 2020 15:18:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:27:31

US3492228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:27:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:27:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:27:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Sep 2020 15:27:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:27:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:27:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Sep 2020 15:28:37
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Sep 2020 15:28:37
User entered '09:52' reason for change: Per Query Resolution	(b) (4), (b) (6)	22 Sep 2020 15:28:37
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 15:27:31
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 15:27:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered '22 Sep 2020 09:52'	System	22 Sep 2020 15:28:37
User entered empty.	System	22 Sep 2020 15:27:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Sep 2020 15:28:37
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Sep 2020 15:28:37
User entered '36.4' C reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 15:28:37
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 15:27:31
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 15:27:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User closed query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	(b) (4) System	22 Sep 2020 15:29:13
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 15:28:57
Query 'Data is required. Please provide.' answered by System data change (Site from System).		22 Sep 2020 15:28:57
User opened query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	System	22 Sep 2020 15:28:57
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 15:28:57
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 15:28:37
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 15:27:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'tympanic' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:29:13
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 15:27:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Sep 2020 15:28:37
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Sep 2020 15:28:37
User entered '60' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 15:28:37
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 15:27:31
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 15:27:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered 'bpm'	System	22 Sep 2020 15:28:37
User entered empty.	System	22 Sep 2020 15:27:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Sep 2020 15:28:37
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Sep 2020 15:28:37
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 15:28:37
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 15:27:31
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 15:27:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered 'breaths/min'	System	22 Sep 2020 15:28:37
User entered empty.	System	22 Sep 2020 15:27:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Sep 2020 15:28:37
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Sep 2020 15:28:37
User entered '115' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 15:28:37
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 15:27:31
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 15:27:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered 'mmHg'	System	22 Sep 2020 15:28:37
User entered empty.	System	22 Sep 2020 15:27:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Sep 2020 15:28:37
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Sep 2020 15:28:37
User entered '81' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 15:28:37
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 15:27:31
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 15:27:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered 'mmHg'	System	22 Sep 2020 15:28:37
User entered empty.	System	22 Sep 2020 15:27:31

US3492228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:27:31

US3492228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:27:31

US3492228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Sep 2020 15:27:31

US3492228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Sep 2020 15:52:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 15:52:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Lorna Sanchez McCann (b) (4)	22 Sep 2020 15:52:46
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 15:27:31
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 15:27:31

US3492228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '22 Sep 2020' reason for change: Data Entry Error	(b) (4)	22 Sep 2020 15:52:46
User entered empty.	Lorna Sanchez McCann (b) (4), (b) (6)	22 Sep 2020 15:27:31

US3492228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '10:50' reason for change: Data Entry Error	(b) (4)	22 Sep 2020 15:52:46
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 15:27:31

US3492228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered '22 Sep 2020 10:50'	System	22 Sep 2020 15:52:46
User entered empty.	System	22 Sep 2020 15:27:31

US3492228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 13:49:56
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Marla Schwarber (b) (4) (b) (4)	23 Sep 2020 17:37:32
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	22 Sep 2020 15:52:46
User entered '35.3' C reason for change: Data Entry Error	Lorna Sanchez McCann (b) (4)	22 Sep 2020 15:52:46
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 15:27:31

US3492228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	22 Sep 2020 15:52:46
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 15:27:31

US3492228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'tympanic' reason for change: Data Entry Error	(b) (4)	22 Sep 2020 15:52:46
User entered empty.	Lorna Sanchez McCann (b) (4), (b) (6)	22 Sep 2020 15:27:31

US3492228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '69' reason for change: Data Entry Error	(b) (4)	22 Sep 2020 15:52:46
User entered empty.	Lorna Sanchez McCann (b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	22 Sep 2020 15:27:31

US3492228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered 'bpm'	System	22 Sep 2020 15:52:46
User entered empty.	System	22 Sep 2020 15:27:31

US3492228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '12' reason for change: Data Entry Error	(b) (4)	22 Sep 2020 15:52:46
User entered empty.	Lorna Sanchez McCann (b) (4)	22 Sep 2020 15:27:31
	(b) (4), (b) (6)	

US3492228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered 'breaths/min'	System	22 Sep 2020 15:52:46
User entered empty.	System	22 Sep 2020 15:27:31

US3492228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '114' reason for change: Data Entry Error	(b) (4)	22 Sep 2020 15:52:46
User entered empty.	Lorna Sanchez McCann (b) (4)	22 Sep 2020 15:27:31
	(b) (4), (b) (6)	

US3492228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered 'mmHg'	System	22 Sep 2020 15:52:46
User entered empty.	System	22 Sep 2020 15:27:31

US3492228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '80' reason for change: Data Entry Error	(b) (4)	22 Sep 2020 15:52:46
User entered empty.	Lorna Sanchez McCann (b) (4), (b) (6)	22 Sep 2020 15:27:31

US3492228

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered 'mmHg'	System	22 Sep 2020 15:52:46
User entered empty.	System	22 Sep 2020 15:27:31

US3492228

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User closed query 'Per CDM: Per CCG, If Screening and Visit 1 Day 1 dosing are done on the same day, physical examination page should be marked as 'No' at VID1 to avoid duplication. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 05:08:02
Query 'Per CDM: Per CCG, If Screening and Visit 1 Day 1 dosing are done on the same day, physical examination page should be marked as 'No' at VID1 to avoid duplication. Please update accordingly.' answered with 'updated' (Site from DM).	Lorna Sanchez McCann (b) (4)	05 Oct 2020 19:10:14
User entered 'No (N)' reason for change: Per Query Resolution	Lorna Sanchez McCann (b) (4)	05 Oct 2020 19:10:09
User opened query 'Per CDM: Per CCG, If Screening and Visit 1 Day 1 dosing are done on the same day, physical examination page should be marked as 'No' at VID1 to avoid duplication. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 14:54:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 15:29:27

US3492228

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered empty; reason for change Per Query Resolution	(b) (4)	05 Oct 2020 19:10:09
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 15:29:27

US3492228

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User closed query 'Per CDM: Per CCG, If Screening and Visit 1 Day 1 dosing are done on the same day, pregnancy test page should be marked as 'No' at VID1 to avoid duplication. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 05:07:41
Query 'Per CDM: Per CCG, If Screening and Visit 1 Day 1 dosing are done on the same day, pregnancy test page should be marked as 'No' at VID1 to avoid duplication. Please update accordingly.' answered with 'updated' (Site from DM).	Lorna Sanchez McCann (b) (4)	05 Oct 2020 19:06:26
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 19:06:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Oct 2020 19:06:19
User entered 'No (N)' reason for change: Per Query Resolution	Lorna Sanchez McCann (b) (4)	05 Oct 2020 19:06:19
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 19:06:13
User entered empty; reason for change Per Query Resolution	Lorna Sanchez McCann (b) (4)	05 Oct 2020 19:06:13
User opened query 'Per CDM: Per CCG, If Screening and Visit 1 Day 1 dosing are done on the same day, pregnancy test page should be marked as 'No' at VID1 to avoid duplication. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 14:54:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 15:31:37

US3492228

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered empty; reason for change Per Query Resolution	(b) (4)	05 Oct 2020 19:06:13
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 15:31:37

US3492228

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered empty; reason for change Per Query Resolution	(b) (4)	05 Oct 2020 19:06:13
User entered 'Urine (URINE)'	(b) (4), (b) (6)	22 Sep 2020 15:31:37

US3492228

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:58
User entered empty; reason for change Per Query Resolution	Lorna Sanchez McCann (b) (4)	05 Oct 2020 19:06:13
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	22 Sep 2020 15:31:37

US3492228

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User closed query 'Per CDM: Please provide a response to Was FSH sample collected?' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 05:03:59
Query 'Per CDM: Please provide a response to Was FSH sample collected?' answered with 'corrected' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	19 Mar 2021 21:32:20
Signature has been broken.	Marla Schwarber (b) (4) (b) (4)	19 Mar 2021 21:32:15
User entered 'No (N)' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	19 Mar 2021 21:32:15
User opened query 'Per CDM: Please provide a response to Was FSH sample collected?' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 20:26:33
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:58
User entered empty; reason for change Per Query Resolution	Lorna Sanchez McCann (b) (4)	05 Oct 2020 19:06:13
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 15:31:37

US3492228

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered empty; reason for change Per Query Resolution	(b) (4)	05 Oct 2020 19:06:13
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 15:31:37

US3492228

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered empty; reason for change Data Entry Error	(b) (4)	05 Oct 2020 19:06:13
User entered '10:03'	(b) (4), (b) (6)	22 Sep 2020 15:31:37

US3492228

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered empty.	System	05 Oct 2020 19:06:13
User entered '22 Sep 2020 10:03'	System	22 Sep 2020 15:31:37

US3492228

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	22 Sep 2020 15:50:42

US3492228

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:58
User entered empty.	Lorna Sanchez McCann (b) (4)	22 Sep 2020 15:50:42

US3492228

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered empty.	(b) (4) Lorna Sanchez McCann (b) (4)	22 Sep 2020 15:50:42

US3492228

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered 'MRNA-1273 OR PLACEBO'	System	22 Sep 2020 15:50:42

US3492228

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '22 Sep 2020'	(b) (4) Lorna Sanchez McCann (b) (4)	22 Sep 2020 15:50:42

US3492228

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '10:45'	(b) (4) Lorna Sanchez McCann (b) (4)	22 Sep 2020 15:50:42

US3492228

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered '22 Sep 2020 10:45'	System	22 Sep 2020 15:50:42

US3492228

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Left Arm (LEFT ARM)'	(b) (4) Lorna Sanchez McCann (b) (4)	22 Sep 2020 15:50:42

US3492228

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered 'ONCE'	System	22 Sep 2020 15:50:42

US3492228

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered 'INTRAMUSCULAR'	System	22 Sep 2020 15:50:42

US3492228

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	22 Sep 2020 15:49:41

US3492228

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '22 Sep 2020'	(b) (4) Lorna Sanchez McCann (b) (4)	22 Sep 2020 15:49:41

US3492228

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:58
User entered '10:08'	Lorna Sanchez McCann (b) (4)	22 Sep 2020 15:49:41

US3492228

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered '22 Sep 2020 10:08'	System	22 Sep 2020 15:49:41

US3492228

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:53:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '22 Sep 2020'	(b) (4) Lorna Sanchez McCann (b) (4)	22 Sep 2020 15:49:58

US3492228

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Lorna Sanchez McCann (b) (4)	22 Sep 2020 15:49:58

US3492228

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	22 Sep 2020 15:49:58

US3492228

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '10:00'	(b) (4) Lorna Sanchez McCann (b) (4)	22 Sep 2020 15:49:58

US3492228

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered '22 Sep 2020 10:00'	System	22 Sep 2020 15:49:58

US3492228

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Lorna Sanchez McCann (b) (4)	22 Sep 2020 15:49:58

US3492228

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'No (N)'	(b) (4) Lorna Sanchez McCann (b) (4)	22 Sep 2020 15:49:58

US3492228

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:58
User entered empty.	Lorna Sanchez McCann (b) (4)	22 Sep 2020 15:49:58

US3492228

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered empty.	System	22 Sep 2020 15:49:58

US3492228

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	22 Sep 2020 15:50:11

US3492228

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered '1'	System	22 Sep 2020 15:50:11

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Sep 2020 15:50:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T11:05:43', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '4feaecb6-05c5-4ee9-bbe2-0ed31e53d814' User entered 'Yes (Y)'	System	22 Sep 2020 16:14:05
	System	22 Sep 2020 16:14:05

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T11:13:54', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '4feaecb6-05c5-4ee9-bbe2-0ed31e53d814' User entered '95.6'	System	22 Sep 2020 16:14:05
	System	22 Sep 2020 16:14:05

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T11:13:59', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '4feaecb6-05c5-4ee9-bbe2-0ed31e53d814' User entered 'No (N)'	System	22 Sep 2020 16:14:05
	System	22 Sep 2020 16:14:05

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T11:14:03', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '4feaecb6-05c5-4ee9-bbe2-0ed31e53d814' User entered '22 Sep 2020 11:14'	System	22 Sep 2020 16:14:05
	System	22 Sep 2020 16:14:05

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '22 Sep 2020 11:05'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '22 Sep 2020 13:35'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Sep 2020 15:50:42
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T17:50:57', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '28e87e29-7b0a-45d0-90bc-baa915eae1e7'	System	22 Sep 2020 22:51:12
User entered 'Yes (Y)'	System	22 Sep 2020 22:51:12

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T17:51:01', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '28e87e29-7b0a-45d0-90bc-baa915eae1e7'	System	22 Sep 2020 22:51:12
User entered '96.0'	System	22 Sep 2020 22:51:12

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T17:51:04', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '28e87e29-7b0a-45d0-90bc-baa915eae1e7'	System	22 Sep 2020 22:51:12
User entered 'No (N)'	System	22 Sep 2020 22:51:12

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T17:51:11', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '28e87e29-7b0a-45d0-90bc-baa915eae1e7' User entered '22 Sep 2020 17:51'	System	22 Sep 2020 22:51:12
	System	22 Sep 2020 22:51:12

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '22 Sep 2020 14:30'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Sep 2020 15:50:42
User entered 'Day 2'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:53:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-23T21:04:26', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'e661af33-6dd1-44ed-8e35-6bc2c43f9d6e' User entered 'Yes (Y)'	System	24 Sep 2020 02:07:08
	System	24 Sep 2020 02:07:08

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:53:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-23T21:06:59', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'e661af33-6dd1-44ed-8e35-6bc2c43f9d6e' User entered '96.1'	System	24 Sep 2020 02:07:08
	System	24 Sep 2020 02:07:08

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-23T21:07:03', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'e661af33-6dd1-44ed-8e35-6bc2c43f9d6e' User entered 'No (N)'	System	24 Sep 2020 02:07:08
	System	24 Sep 2020 02:07:08

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-23T21:07:05', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'e661af33-6dd1-44ed-8e35-6bc2c43f9d6e' User entered '23 Sep 2020 21:07'	System	24 Sep 2020 02:07:08
	System	24 Sep 2020 02:07:08

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Sep 2020 15:50:42
User entered 'Day 3'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:53:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-24T22:59:37', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'ce815398-dc62-4a73-8c2e-421ec7a89568' User entered 'Yes (Y)'	System	25 Sep 2020 04:01:21
	System	25 Sep 2020 04:01:21

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:53:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-24T23:01:10', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'ce815398-dc62-4a73-8c2e-421ec7a89568' User entered '95.7'	System	25 Sep 2020 04:01:21
	System	25 Sep 2020 04:01:21

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-24T23:01:13', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'ce815398-dc62-4a73-8c2e-421ec7a89568' User entered 'No (N)'	System	25 Sep 2020 04:01:21
	System	25 Sep 2020 04:01:21

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-24T23:01:18', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'ce815398-dc62-4a73-8c2e-421ec7a89568' User entered '24 Sep 2020 23:01'	System	25 Sep 2020 04:01:21
	System	25 Sep 2020 04:01:21

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Sep 2020 15:50:42
User entered 'Day 4'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:53:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-25T17:57:31', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '2abbec4c-bba6-4f38-aff8-f93e2c3753d2'	System	25 Sep 2020 22:57:45
User entered 'Yes (Y)'	System	25 Sep 2020 22:57:45

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:53:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-25T17:57:36', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '2abbec4c-bba6-4f38-aff8-f93e2c3753d2' User entered '97.6'	System	25 Sep 2020 22:57:45
	System	25 Sep 2020 22:57:45

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-25T17:57:38', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '2abbec4c-bba6-4f38-aff8-f93e2c3753d2'	System	25 Sep 2020 22:57:45
User entered 'No (N)'	System	25 Sep 2020 22:57:45

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-25T17:57:41', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '2abbec4c-bba6-4f38-aff8-f93e2c3753d2' User entered '25 Sep 2020 17:57'	System	25 Sep 2020 22:57:45
	System	25 Sep 2020 22:57:45

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Sep 2020 15:50:42
User entered 'Day 5'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:53:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-26T12:27:43', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '22a95088-d86a-4dee-b3f6-05562dd7d861' User entered 'Yes (Y)'	System	26 Sep 2020 17:28:15
	System	26 Sep 2020 17:28:15

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:53:02

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-26T12:27:46', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '22a95088-d86a-4dee-b3f6-05562dd7d861' User entered '97.2'	System	26 Sep 2020 17:28:15
	System	26 Sep 2020 17:28:15

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-26T12:28:04', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '22a95088-d86a-4dee-b3f6-05562dd7d861' User entered 'Yes (Y)'	System	26 Sep 2020 17:28:15
	System	26 Sep 2020 17:28:15

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
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 'medication taken listed in medication log' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 15:12:12
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.' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 20:13:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-26T12:28:09', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '22a95088-d86a-4dee-b3f6-05562dd7d861'	System	26 Sep 2020 17:28:15
User entered '1'	System	26 Sep 2020 17:28:15

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:53:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-26T12:28:09', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '22a95088-d86a-4dee-b3f6-05562dd7d861' User entered '0'	System	26 Sep 2020 17:28:15
	System	26 Sep 2020 17:28:15

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-26T12:28:13', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '22a95088-d86a-4dee-b3f6-05562dd7d861' User entered '26 Sep 2020 12:28'	System	26 Sep 2020 17:28:15
	System	26 Sep 2020 17:28:15

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Sep 2020 15:50:42
User entered 'Day 6'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:53:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-27T15:47:24', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '33e661b8-895c-448c-8a1b-0b673c9162e9' User entered 'Yes (Y)'	System	27 Sep 2020 20:48:43
	System	27 Sep 2020 20:48:43

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:53:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-27T15:48:37', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '33e661b8-895c-448c-8a1b-0b673c9162e9' User entered '97.3'	System	27 Sep 2020 20:48:43
	System	27 Sep 2020 20:48:43

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-27T15:48:40', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '33e661b8-895c-448c-8a1b-0b673c9162e9' User entered 'No (N)'	System	27 Sep 2020 20:48:43
	System	27 Sep 2020 20:48:43

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-27T15:48:42', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '33e661b8-895c-448c-8a1b-0b673c9162e9' User entered '27 Sep 2020 15:48'	System	27 Sep 2020 20:48:43
	System	27 Sep 2020 20:48:43

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Sep 2020 15:50:42
User entered 'Day 7'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:53:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-28T21:51:17', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'b5b131bd-9d0a-4fbf-89dd-2406874de85f' User entered 'Yes (Y)'	System	29 Sep 2020 02:51:44
	System	29 Sep 2020 02:51:44

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:53:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-28T21:51:38', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'b5b131bd-9d0a-4fbf-89dd-2406874de85f' User entered '96.4'	System	29 Sep 2020 02:51:44
	System	29 Sep 2020 02:51:44

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-28T21:51:41', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'b5b131bd-9d0a-4fbf-89dd-2406874de85f' User entered 'No (N)'	System	29 Sep 2020 02:51:44
	System	29 Sep 2020 02:51:44

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-28T21:51:42', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'b5b131bd-9d0a-4fbf-89dd-2406874de85f' User entered '28 Sep 2020 21:51'	System	29 Sep 2020 02:51:44
	System	29 Sep 2020 02:51:44

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Sep 2020 15:50:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T11:14:14', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '0b09cc2c-de8f-45cf-8d5d-670177f27328'	System	22 Sep 2020 16:14:46
User entered 'None (1)'	System	22 Sep 2020 16:14:46

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T11:14:26', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '0b09cc2c-de8f-45cf-8d5d-670177f27328'	System	22 Sep 2020 16:14:46
User entered 'No (N)'	System	22 Sep 2020 16:14:46

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T11:14:34', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '0b09cc2c-de8f-45cf-8d5d-670177f27328'	System	22 Sep 2020 16:14:46
User entered 'No (N)'	System	22 Sep 2020 16:14:46

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T11:14:41', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '0b09cc2c-de8f-45cf-8d5d-670177f27328'	System	22 Sep 2020 16:14:46
User entered 'None (1)'	System	22 Sep 2020 16:14:46

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T11:14:44', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '0b09cc2c-de8f-45cf-8d5d-670177f27328'	System	22 Sep 2020 16:14:46
User entered '22 Sep 2020 11:14'	System	22 Sep 2020 16:14:46

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '22 Sep 2020 11:05'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '22 Sep 2020 13:35'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Sep 2020 15:50:42
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T17:51:17', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'df2e69e1-cebb-4133-a75e-4fb2677db1f3'	System	22 Sep 2020 22:51:44
User entered 'None (1)'	System	22 Sep 2020 22:51:44

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T17:51:20', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'df2e69e1-cebb-4133-a75e-4fb2677db1f3'	System	22 Sep 2020 22:51:44
User entered 'No (N)'	System	22 Sep 2020 22:51:44

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T17:51:22', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'df2e69e1-cebb-4133-a75e-4fb2677db1f3'	System	22 Sep 2020 22:51:44
User entered 'No (N)'	System	22 Sep 2020 22:51:44

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T17:51:36', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'df2e69e1-cebb-4133-a75e-4fb2677db1f3'	System	22 Sep 2020 22:51:44
User entered 'None (1)'	System	22 Sep 2020 22:51:44

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T17:51:40', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'df2e69e1-cebb-4133-a75e-4fb2677db1f3' User entered '22 Sep 2020 17:51'	System	22 Sep 2020 22:51:44
	System	22 Sep 2020 22:51:44

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '22 Sep 2020 14:30'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Sep 2020 15:50:42
User entered 'Day 2'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-23T14:26:20', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '682025d6-c67f-4663-9dd0-96e9f81f3745'	System	23 Sep 2020 19:26:31
User entered 'None (1)'	System	23 Sep 2020 19:26:31

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-23T14:26:18', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '682025d6-c67f-4663-9dd0-96e9f81f3745'	System	23 Sep 2020 19:26:31
User entered 'No (N)'	System	23 Sep 2020 19:26:31

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-23T14:26:21', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '682025d6-c67f-4663-9dd0-96e9f81f3745'	System	23 Sep 2020 19:26:31
User entered 'No (N)'	System	23 Sep 2020 19:26:31

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-23T14:26:24', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '682025d6-c67f-4663-9dd0-96e9f81f3745'	System	23 Sep 2020 19:26:31
User entered 'None (1)'	System	23 Sep 2020 19:26:31

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-23T14:26:27', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '682025d6-c67f-4663-9dd0-96e9f81f3745' User entered '23 Sep 2020 14:26'	System	23 Sep 2020 19:26:31
	System	23 Sep 2020 19:26:31

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Sep 2020 15:50:42
User entered 'Day 3'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-24T20:17:50', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'd3e51ec2-96c1-41d8-8bd5-7ae07bdcf926'	System	25 Sep 2020 01:17:59
User entered 'None (1)'	System	25 Sep 2020 01:17:59

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-24T20:17:49', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'd3e51ec2-96c1-41d8-8bd5-7ae07bdcf926'	System	25 Sep 2020 01:17:59
User entered 'No (N)'	System	25 Sep 2020 01:17:59

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-24T20:17:48', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'd3e51ec2-96c1-41d8-8bd5-7ae07bdcf926' User entered 'No (N)'	System	25 Sep 2020 01:17:59
	System	25 Sep 2020 01:17:59

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-24T20:17:54', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'd3e51ec2-96c1-41d8-8bd5-7ae07bdcf926'	System	25 Sep 2020 01:17:59
User entered 'None (1)'	System	25 Sep 2020 01:17:59

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-24T20:17:56', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'd3e51ec2-96c1-41d8-8bd5-7ae07bdcf926' User entered '24 Sep 2020 20:17'	System	25 Sep 2020 01:17:59
	System	25 Sep 2020 01:17:59

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Sep 2020 15:50:42
User entered 'Day 4'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-25T17:56:57', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'e831f289-27a3-420f-acfd-069a894ff472'	System	25 Sep 2020 22:57:08
User entered 'None (1)'	System	25 Sep 2020 22:57:08

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-25T17:56:59', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'e831f289-27a3-420f-acfd-069a894ff472'	System	25 Sep 2020 22:57:08
User entered 'No (N)'	System	25 Sep 2020 22:57:08

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-25T17:57:01', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'e831f289-27a3-420f-acfd-069a894ff472'	System	25 Sep 2020 22:57:08
User entered 'No (N)'	System	25 Sep 2020 22:57:08

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-25T17:57:03', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'e831f289-27a3-420f-acfd-069a894ff472'	System	25 Sep 2020 22:57:08
User entered 'None (1)'	System	25 Sep 2020 22:57:08

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-25T17:57:05', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'e831f289-27a3-420f-acfd-069a894ff472'	System	25 Sep 2020 22:57:08
User entered '25 Sep 2020 17:57'	System	25 Sep 2020 22:57:08

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Sep 2020 15:50:42
User entered 'Day 5'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-26T12:25:16', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'e3507d76-7ffe-4dc3-801f-3e91d7423aa6'	System	26 Sep 2020 17:25:28
User entered 'None (1)'	System	26 Sep 2020 17:25:28

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-26T12:25:19', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'e3507d76-7ffe-4dc3-801f-3e91d7423aa6'	System	26 Sep 2020 17:25:28
User entered 'No (N)'	System	26 Sep 2020 17:25:28

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-26T12:25:20', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'e3507d76-7ffe-4dc3-801f-3e91d7423aa6'	System	26 Sep 2020 17:25:28
User entered 'No (N)'	System	26 Sep 2020 17:25:28

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-26T12:25:22', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'e3507d76-7ffe-4dc3-801f-3e91d7423aa6'	System	26 Sep 2020 17:25:28
User entered 'None (1)'	System	26 Sep 2020 17:25:28

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-26T12:25:24', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'e3507d76-7ffe-4dc3-801f-3e91d7423aa6'	System	26 Sep 2020 17:25:28
User entered '26 Sep 2020 12:25'	System	26 Sep 2020 17:25:28

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Sep 2020 15:50:42
User entered 'Day 6'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-27T15:48:58', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'fec667fc-aa2e-493f-8425-05997788b87c'	System	27 Sep 2020 20:49:08
User entered 'None (1)'	System	27 Sep 2020 20:49:08

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-27T15:49:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'fec667fc-aa2e-493f-8425-05997788b87c' User entered 'No (N)'	System	27 Sep 2020 20:49:08
	System	27 Sep 2020 20:49:08

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-27T15:49:03', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'fec667fc-aa2e-493f-8425-05997788b87c' User entered 'No (N)'	System	27 Sep 2020 20:49:08
	System	27 Sep 2020 20:49:08

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-27T15:49:04', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'fec667fc-aa2e-493f-8425-05997788b87c'	System	27 Sep 2020 20:49:08
User entered 'None (1)'	System	27 Sep 2020 20:49:08

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-27T15:49:06', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'fec667fc-aa2e-493f-8425-05997788b87c' User entered '27 Sep 2020 15:49'	System	27 Sep 2020 20:49:08
	System	27 Sep 2020 20:49:08

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Sep 2020 15:50:42
User entered 'Day 7'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-28T21:51:03', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '2a645724-951b-4a9a-b447-d8db17607621'	System	29 Sep 2020 02:51:13
User entered 'None (1)'	System	29 Sep 2020 02:51:13

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-28T21:51:05', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '2a645724-951b-4a9a-b447-d8db17607621' User entered 'No (N)'	System	29 Sep 2020 02:51:13
	System	29 Sep 2020 02:51:13

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-28T21:51:07', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '2a645724-951b-4a9a-b447-d8db17607621' User entered 'No (N)'	System	29 Sep 2020 02:51:13
	System	29 Sep 2020 02:51:13

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-28T21:51:09', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '2a645724-951b-4a9a-b447-d8db17607621'	System	29 Sep 2020 02:51:13
User entered 'None (1)'	System	29 Sep 2020 02:51:13

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-28T21:51:11', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '2a645724-951b-4a9a-b447-d8db17607621' User entered '28 Sep 2020 21:51'	System	29 Sep 2020 02:51:13
	System	29 Sep 2020 02:51:13

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Sep 2020 15:50:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T11:14:48', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9bfc6be-3af5-4063-8210-6172ca21efab' User entered 'None (0)'	System	22 Sep 2020 16:15:10
	System	22 Sep 2020 16:15:10

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T11:14:51', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9bfc6be-3af5-4063-8210-6172ca21efab' User entered 'None (0)'	System	22 Sep 2020 16:15:10
	System	22 Sep 2020 16:15:10

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T11:14:53', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9bfc6be-3af5-4063-8210-6172ca21efab' User entered 'None (0)'	System	22 Sep 2020 16:15:10
	System	22 Sep 2020 16:15:10

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T11:14:55', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9bfc6be-3af5-4063-8210-6172ca21efab' User entered 'None (0)'	System	22 Sep 2020 16:15:10
	System	22 Sep 2020 16:15:10

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T11:14:57', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9bfc6be-3af5-4063-8210-6172ca21efab' User entered 'None (0)'	System	22 Sep 2020 16:15:10
	System	22 Sep 2020 16:15:10

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T11:14:59', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9bfc6be-3af5-4063-8210-6172ca21efab' User entered 'None (0)'	System	22 Sep 2020 16:15:10
	System	22 Sep 2020 16:15:10

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T11:15:04', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9bfc6be-3af5-4063-8210-6172ca21efab' User entered 'No (N)'	System	22 Sep 2020 16:15:10
	System	22 Sep 2020 16:15:10

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T11:15:06', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9bfc66be-3af5-4063-8210-6172ca21efab' User entered '22 Sep 2020 11:15'	System	22 Sep 2020 16:15:10
	System	22 Sep 2020 16:15:10

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '22 Sep 2020 11:05'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '22 Sep 2020 13:35'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Sep 2020 15:50:42
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T17:51:44', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '2c960c73-d647-4a21-84f4-c9d94fec7e2e' User entered 'None (0)'	System	22 Sep 2020 22:52:10
	System	22 Sep 2020 22:52:10

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T17:51:55', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '2c960c73-d647-4a21-84f4-c9d94fec7e2e' User entered 'None (0)'	System	22 Sep 2020 22:52:10
	System	22 Sep 2020 22:52:10

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T17:51:57', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '2c960c73-d647-4a21-84f4-c9d94fec7e2e' User entered 'None (0)'	System	22 Sep 2020 22:52:10
	System	22 Sep 2020 22:52:10

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T17:51:59', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '2c960c73-d647-4a21-84f4-c9d94fec7e2e' User entered 'None (0)'	System	22 Sep 2020 22:52:10
	System	22 Sep 2020 22:52:10

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T17:52:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '2c960c73-d647-4a21-84f4-c9d94fec7e2e' User entered 'None (0)'	System	22 Sep 2020 22:52:10
	System	22 Sep 2020 22:52:10

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T17:52:02', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '2c960c73-d647-4a21-84f4-c9d94fec7e2e' User entered 'None (0)'	System	22 Sep 2020 22:52:10
	System	22 Sep 2020 22:52:10

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T17:52:05', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '2c960c73-d647-4a21-84f4-c9d94fec7e2e' User entered 'No (N)'	System	22 Sep 2020 22:52:10
	System	22 Sep 2020 22:52:10

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-22T17:52:08', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '2c960c73-d647-4a21-84f4-c9d94fec7e2e' User entered '22 Sep 2020 17:52'	System	22 Sep 2020 22:52:10
	System	22 Sep 2020 22:52:10

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '22 Sep 2020 14:30'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Sep 2020 15:50:42
User entered 'Day 2'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-23T14:26:31', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '26f3781f-ffc0-4f39-b15d-ce10dd56a1ad' User entered 'None (0)'	System	23 Sep 2020 19:26:48
	System	23 Sep 2020 19:26:48

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-23T14:26:32', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '26f3781f-ffc0-4f39-b15d-ce10dd56a1ad' User entered 'None (0)'	System	23 Sep 2020 19:26:48
	System	23 Sep 2020 19:26:48

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-23T14:26:34', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '26f3781f-ffc0-4f39-b15d-ce10dd56a1ad' User entered 'None (0)'	System	23 Sep 2020 19:26:48
	System	23 Sep 2020 19:26:48

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-23T14:26:35', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '26f3781f-ffc0-4f39-b15d-ce10dd56a1ad' User entered 'None (0)'	System	23 Sep 2020 19:26:48
	System	23 Sep 2020 19:26:48

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-23T14:26:37', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '26f3781f-ffc0-4f39-b15d-ce10dd56a1ad' User entered 'None (0)'	System	23 Sep 2020 19:26:48
	System	23 Sep 2020 19:26:48

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-23T14:26:39', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '26f3781f-ffc0-4f39-b15d-ce10dd56a1ad'	System	23 Sep 2020 19:26:48
User entered 'None (0)'	System	23 Sep 2020 19:26:48

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-23T14:26:43', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '26f3781f-ffc0-4f39-b15d-ce10dd56a1ad'	System	23 Sep 2020 19:26:48
User entered 'No (N)'	System	23 Sep 2020 19:26:48

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-23T14:26:45', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '26f3781f-ffc0-4f39-b15d-ce10dd56a1ad' User entered '23 Sep 2020 14:26'	System	23 Sep 2020 19:26:48
	System	23 Sep 2020 19:26:48

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Sep 2020 15:50:42
User entered 'Day 3'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-24T20:18:01', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'bf7514fb-b688-448d-b0a7-51e1056a34c0'	System	25 Sep 2020 01:18:19
User entered 'None (0)'	System	25 Sep 2020 01:18:19

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-24T20:18:03', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'bf7514fb-b688-448d-b0a7-51e1056a34c0' User entered 'None (0)'	System	25 Sep 2020 01:18:19
	System	25 Sep 2020 01:18:19

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-24T20:18:05', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'bf7514fb-b688-448d-b0a7-51e1056a34c0' User entered 'None (0)'	System	25 Sep 2020 01:18:19
	System	25 Sep 2020 01:18:19

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-24T20:18:06', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'bf7514fb-b688-448d-b0a7-51e1056a34c0' User entered 'None (0)'	System	25 Sep 2020 01:18:19
	System	25 Sep 2020 01:18:19

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-24T20:18:08', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'bf7514fb-b688-448d-b0a7-51e1056a34c0' User entered 'None (0)'	System	25 Sep 2020 01:18:19
	System	25 Sep 2020 01:18:19

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-24T20:18:11', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'bf7514fb-b688-448d-b0a7-51e1056a34c0' User entered 'None (0)'	System	25 Sep 2020 01:18:19
	System	25 Sep 2020 01:18:19

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-24T20:18:14', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'bf7514fb-b688-448d-b0a7-51e1056a34c0' User entered 'No (N)'	System	25 Sep 2020 01:18:19
	System	25 Sep 2020 01:18:19

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-24T20:18:16', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'bf7514fb-b688-448d-b0a7-51e1056a34c0' User entered '24 Sep 2020 20:18'	System	25 Sep 2020 01:18:19
	System	25 Sep 2020 01:18:19

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Sep 2020 15:50:42
User entered 'Day 4'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-25T17:57:09', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'e78d5106-fd70-44d9-895c-26d6761995a6' User entered 'None (0)'	System	25 Sep 2020 22:57:24
	System	25 Sep 2020 22:57:24

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-25T17:57:10', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'e78d5106-fd70-44d9-895c-26d6761995a6' User entered 'None (0)'	System	25 Sep 2020 22:57:24
	System	25 Sep 2020 22:57:24

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-25T17:57:12', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'e78d5106-fd70-44d9-895c-26d6761995a6' User entered 'None (0)'	System	25 Sep 2020 22:57:24
	System	25 Sep 2020 22:57:24

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-25T17:57:14', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'e78d5106-fd70-44d9-895c-26d6761995a6' User entered 'None (0)'	System	25 Sep 2020 22:57:24
	System	25 Sep 2020 22:57:24

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-25T17:57:15', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'e78d5106-fd70-44d9-895c-26d6761995a6' User entered 'None (0)'	System	25 Sep 2020 22:57:24
	System	25 Sep 2020 22:57:24

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-25T17:57:17', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'e78d5106-fd70-44d9-895c-26d6761995a6' User entered 'None (0)'	System	25 Sep 2020 22:57:24
	System	25 Sep 2020 22:57:24

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-25T17:57:19', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'e78d5106-fd70-44d9-895c-26d6761995a6' User entered 'No (N)'	System	25 Sep 2020 22:57:24
	System	25 Sep 2020 22:57:24

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-25T17:57:21', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'e78d5106-fd70-44d9-895c-26d6761995a6' User entered '25 Sep 2020 17:57'	System	25 Sep 2020 22:57:24
	System	25 Sep 2020 22:57:24

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Sep 2020 15:50:42
User entered 'Day 5'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-26T12:25:31', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'a9177039-3cf2-456d-a763-adceb8200783'	System	26 Sep 2020 17:25:46
User entered 'No interference with activity (1)'	System	26 Sep 2020 17:25:46

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-26T12:25:33', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'a9177039-3cf2-456d-a763-adceb8200783' User entered 'None (0)'	System	26 Sep 2020 17:25:46
	System	26 Sep 2020 17:25:46

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-26T12:25:35', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'a9177039-3cf2-456d-a763-adceb8200783' User entered 'None (0)'	System	26 Sep 2020 17:25:46
	System	26 Sep 2020 17:25:46

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-26T12:25:37', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'a9177039-3cf2-456d-a763-adceb8200783' User entered 'None (0)'	System	26 Sep 2020 17:25:46
	System	26 Sep 2020 17:25:46

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-26T12:25:38', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'a9177039-3cf2-456d-a763-adceb8200783' User entered 'None (0)'	System	26 Sep 2020 17:25:46
	System	26 Sep 2020 17:25:46

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-26T12:25:40', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'a9177039-3cf2-456d-a763-adceb8200783' User entered 'None (0)'	System	26 Sep 2020 17:25:46
	System	26 Sep 2020 17:25:46

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-26T12:25:43', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'a9177039-3cf2-456d-a763-adceb8200783' User entered 'No (N)'	System	26 Sep 2020 17:25:46
	System	26 Sep 2020 17:25:46

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-26T12:25:45', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'a9177039-3cf2-456d-a763-adceb8200783' User entered '26 Sep 2020 12:25'	System	26 Sep 2020 17:25:46
	System	26 Sep 2020 17:25:46

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Sep 2020 15:50:42
User entered 'Day 6'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-27T15:49:11', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9429de0a-f05c-4633-afdd-6a72eba633a9' User entered 'None (0)'	System	27 Sep 2020 20:49:26
	System	27 Sep 2020 20:49:26

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-27T15:49:13', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9429de0a-f05c-4633-afdd-6a72eba633a9' User entered 'None (0)'	System	27 Sep 2020 20:49:26
	System	27 Sep 2020 20:49:26

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-27T15:49:15', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9429de0a-f05c-4633-afdd-6a72eba633a9' User entered 'None (0)'	System	27 Sep 2020 20:49:26
	System	27 Sep 2020 20:49:26

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-27T15:49:16', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9429de0a-f05c-4633-afdd-6a72eba633a9' User entered 'None (0)'	System	27 Sep 2020 20:49:26
	System	27 Sep 2020 20:49:26

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-27T15:49:18', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9429de0a-f05c-4633-afdd-6a72eba633a9' User entered 'None (0)'	System	27 Sep 2020 20:49:26
	System	27 Sep 2020 20:49:26

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-27T15:49:19', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9429de0a-f05c-4633-afdd-6a72eba633a9' User entered 'None (0)'	System	27 Sep 2020 20:49:26
	System	27 Sep 2020 20:49:26

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-27T15:49:22', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9429de0a-f05c-4633-afdd-6a72eba633a9' User entered 'No (N)'	System	27 Sep 2020 20:49:26
	System	27 Sep 2020 20:49:26

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-27T15:49:24', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9429de0a-f05c-4633-afdd-6a72eba633a9' User entered '27 Sep 2020 15:49'	System	27 Sep 2020 20:49:26
	System	27 Sep 2020 20:49:26

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Sep 2020 15:50:42
User entered 'Day 7'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-28T21:50:46', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '699b7652-bcd7-4349-accb-1ac626b83747' User entered 'None (0)'	System	29 Sep 2020 02:51:02
	System	29 Sep 2020 02:51:02

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-28T21:50:48', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '699b7652-bcd7-4349-accb-1ac626b83747' User entered 'None (0)'	System	29 Sep 2020 02:51:02
	System	29 Sep 2020 02:51:02

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-28T21:50:50', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '699b7652-bcd7-4349-accb-1ac626b83747' User entered 'None (0)'	System	29 Sep 2020 02:51:02
	System	29 Sep 2020 02:51:02

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-28T21:50:51', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '699b7652-bcd7-4349-accb-1ac626b83747' User entered 'None (0)'	System	29 Sep 2020 02:51:02
	System	29 Sep 2020 02:51:02

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-28T21:50:54', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '699b7652-bcd7-4349-accb-1ac626b83747' User entered 'None (0)'	System	29 Sep 2020 02:51:02
	System	29 Sep 2020 02:51:02

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-28T21:50:56', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '699b7652-bcd7-4349-accb-1ac626b83747' User entered 'None (0)'	System	29 Sep 2020 02:51:02
	System	29 Sep 2020 02:51:02

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-28T21:50:57', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '699b7652-bcd7-4349-accb-1ac626b83747' User entered 'No (N)'	System	29 Sep 2020 02:51:02
	System	29 Sep 2020 02:51:02

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-09-28T21:51:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '699b7652-bcd7-4349-accb-1ac626b83747' User entered '28 Sep 2020 21:51'	System	29 Sep 2020 02:51:02
	System	29 Sep 2020 02:51:02

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 15:50:42

US3492228

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 15:50:42

US3492228

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	Addis Mekonnen (b) (4) (b) (4)	29 Sep 2020 19:39:17

US3492228

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '29 Sep 2020'	(b) (4) Addis Mekonnen (b) (4)	29 Sep 2020 19:39:17
	(b) (4)	

US3492228

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Addis Mekonnen (b) (4)	29 Sep 2020 19:39:17

US3492228

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered empty.	(b) (4) Addis Mekonnen (b) (4)	29 Sep 2020 19:39:17
	(b) (4)	

US3492228

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	Addis Mekonnen (b) (4) (b) (4)	29 Sep 2020 19:39:20

US3492228

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered '1'	System	29 Sep 2020 19:39:20

US3492228

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 23:06:45

US3492228

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 23:06:45

US3492228

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 23:06:45

US3492228

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 23:06:45

US3492228

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 23:06:50

US3492228

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered '1'	System	07 Oct 2020 23:06:50

US3492228

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	14 Oct 2020 15:01:56

US3492228

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '13 Oct 2020'	(b) (4) Nusirat Williams (b) (4)	14 Oct 2020 15:01:56

US3492228

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nusirat Williams (b) (4)	14 Oct 2020 15:01:56

US3492228

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered empty.	(b) (4) Nusirat Williams (b) (4)	14 Oct 2020 15:01:56

US3492228

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	14 Oct 2020 15:02:02

US3492228

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered '1'	System	14 Oct 2020 15:02:02

US3492228

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:44:47

US3492228

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:44:47

US3492228

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:44:47

US3492228

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered 'VISIT2'	System	22 Oct 2020 16:44:47

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '11:22'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered '22 Oct 2020 11:22'	System	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'EAR'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '71'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered 'bpm'	System	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '20'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered 'breaths/min'	System	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '96'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered 'mmHg'	System	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '66'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered 'mmHg'	System	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Oct 2020 17:17:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 17:17:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 17:17:26
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 16:46:30
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '22 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:17:26
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '12:13' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:17:26
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered '22 Oct 2020 12:13'	System	22 Oct 2020 17:17:26
User entered empty.	System	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '98.0' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:17:26
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:17:26
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Tympanic' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:17:26
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '63' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:17:26
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered 'bpm'	System	22 Oct 2020 17:17:26
User entered empty.	System	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '16' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:17:26
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered 'breaths/min'	System	22 Oct 2020 17:17:26
User entered empty.	System	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '102' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:17:26
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered 'mmHg'	System	22 Oct 2020 17:17:26
User entered empty.	System	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '68' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:17:26
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered 'mmHg'	System	22 Oct 2020 17:17:26
User entered empty.	System	22 Oct 2020 16:46:30

US3492228

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:46:56

US3492228

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:46:56

US3492228

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:47:19

US3492228

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:47:19

US3492228

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:47:19

US3492228

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:47:19

US3492228

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:47:19

US3492228

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:47:19

US3492228

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:47:19

US3492228

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered empty.	System	22 Oct 2020 16:47:19

US3492228

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:14:37

US3492228

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:14:37

US3492228

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:14:37

US3492228

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered 'MRNA-1273 OR PLACEBO'	System	22 Oct 2020 17:14:37

US3492228

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:14:37

US3492228

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '12:09'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:14:37

US3492228

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered '22 Oct 2020 12:09'	System	22 Oct 2020 17:14:37

US3492228

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:14:37

US3492228

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered 'ONCE'	System	22 Oct 2020 17:14:37

US3492228

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered 'INTRAMUSCULAR'	System	22 Oct 2020 17:14:37

US3492228

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:15:07

US3492228

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:15:07

US3492228

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '11:40'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:15:07

US3492228

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered '22 Oct 2020 11:40'	System	22 Oct 2020 17:15:07

US3492228

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:53:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:15:21

US3492228

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	22 Oct 2020 17:15:21

US3492228

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:15:21

US3492228

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '11:46'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:15:21

US3492228

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered '22 Oct 2020 11:46'	System	22 Oct 2020 17:15:21

US3492228

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	22 Oct 2020 17:15:21

US3492228

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:15:21

US3492228

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:15:21

US3492228

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered empty.	System	22 Oct 2020 17:15:21

US3492228

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:15:39

US3492228

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered '1'	System	22 Oct 2020 17:15:39

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Oct 2020 17:14:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T12:37:31', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '6e637e83-6b5c-479b-9d17-7661ff5c0c5f' User entered 'Yes (Y)'	System	22 Oct 2020 17:38:06
	System	22 Oct 2020 17:38:06

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T12:37:48', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '6e637e83-6b5c-479b-9d17-7661ff5c0c5f' User entered '98.0'	System	22 Oct 2020 17:38:06
	System	22 Oct 2020 17:38:06

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T12:38:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '6e637e83-6b5c-479b-9d17-7661ff5c0c5f' User entered 'No (N)'	System	22 Oct 2020 17:38:06
	System	22 Oct 2020 17:38:06

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T12:38:03', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '6e637e83-6b5c-479b-9d17-7661ff5c0c5f' User entered '22 Oct 2020 12:38'	System	22 Oct 2020 17:38:06
	System	22 Oct 2020 17:38:06

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '22 Oct 2020 12:29'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '22 Oct 2020 14:59'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Oct 2020 17:14:37
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T19:11:51', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'dd3de4c6-94dc-44fa-bdd4-0e0c60c24f60' User entered 'Yes (Y)'	System	23 Oct 2020 00:13:29
	System	23 Oct 2020 00:13:29

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T19:13:22', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'dd3de4c6-94dc-44fa-bdd4-0e0c60c24f60' User entered '97.3'	System	23 Oct 2020 00:13:29
	System	23 Oct 2020 00:13:29

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T19:13:24', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'dd3de4c6-94dc-44fa-bdd4-0e0c60c24f60'	System	23 Oct 2020 00:13:29
User entered 'No (N)'	System	23 Oct 2020 00:13:29

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T19:13:26', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'dd3de4c6-94dc-44fa-bdd4-0e0c60c24f60' User entered '22 Oct 2020 19:13'	System	23 Oct 2020 00:13:29
	System	23 Oct 2020 00:13:29

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '22 Oct 2020 15:54'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Oct 2020 17:14:37
User entered 'Day 2'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:53:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-23T20:28:14', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'f5aab9d2-2127-4783-8ea5-e428c0f613cd' User entered 'Yes (Y)'	System	24 Oct 2020 01:30:30
	System	24 Oct 2020 01:30:30

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:53:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-23T20:30:23', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'f5aab9d2-2127-4783-8ea5-e428c0f613cd' User entered '97.1'	System	24 Oct 2020 01:30:30
	System	24 Oct 2020 01:30:30

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-23T20:30:25', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'f5aab9d2-2127-4783-8ea5-e428c0f613cd' User entered 'No (N)'	System	24 Oct 2020 01:30:30
	System	24 Oct 2020 01:30:30

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-23T20:30:28', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'f5aab9d2-2127-4783-8ea5-e428c0f613cd' User entered '23 Oct 2020 20:30'	System	24 Oct 2020 01:30:30
	System	24 Oct 2020 01:30:30

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Oct 2020 17:14:37
User entered 'Day 3'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:53:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-24T16:22:26', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '63aa8b05-fa2f-4a88-84c1-00f4612593d2' User entered 'Yes (Y)'	System	24 Oct 2020 21:30:08
	System	24 Oct 2020 21:30:08

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:53:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-24T16:29:01', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '63aa8b05-fa2f-4a88-84c1-00f4612593d2' User entered '97.7'	System	24 Oct 2020 21:30:08
	System	24 Oct 2020 21:30:08

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-24T16:29:05', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '63aa8b05-fa2f-4a88-84c1-00f4612593d2'	System	24 Oct 2020 21:30:08
User entered 'No (N)'	System	24 Oct 2020 21:30:08

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-24T16:29:06', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '63aa8b05-fa2f-4a88-84c1-00f4612593d2' User entered '24 Oct 2020 16:29'	System	24 Oct 2020 21:30:08
	System	24 Oct 2020 21:30:08

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Oct 2020 17:14:37
User entered 'Day 4'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:53:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-25T18:33:13', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '2d37ed0d-3b14-4964-9e55-6cdb3e414962'	System	25 Oct 2020 23:35:08
User entered 'Yes (Y)'	System	25 Oct 2020 23:35:08

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:53:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-25T18:34:58', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '2d37ed0d-3b14-4964-9e55-6cdb3e414962'	System	25 Oct 2020 23:35:08
User entered '95.5'	System	25 Oct 2020 23:35:08

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-25T18:35:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '2d37ed0d-3b14-4964-9e55-6cdb3e414962'	System	25 Oct 2020 23:35:08
User entered 'No (N)'	System	25 Oct 2020 23:35:08

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-25T18:35:02', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '2d37ed0d-3b14-4964-9e55-6cdb3e414962'	System	25 Oct 2020 23:35:08
User entered '25 Oct 2020 18:35'	System	25 Oct 2020 23:35:08

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Oct 2020 17:14:37
User entered 'Day 5'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:53:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T09:35:15', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '07e6e534-6b9d-4944-907f-3784c61507b7' User entered 'Yes (Y)'	System	27 Oct 2020 14:35:27
	System	27 Oct 2020 14:35:27

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:53:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T09:35:19', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '07e6e534-6b9d-4944-907f-3784c61507b7' User entered '97.2'	System	27 Oct 2020 14:35:27
	System	27 Oct 2020 14:35:27

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T09:35:21', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '07e6e534-6b9d-4944-907f-3784c61507b7'	System	27 Oct 2020 14:35:27
User entered 'No (N)'	System	27 Oct 2020 14:35:27

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T09:35:23', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '07e6e534-6b9d-4944-907f-3784c61507b7' User entered '27 Oct 2020 09:35'	System	27 Oct 2020 14:35:27
	System	27 Oct 2020 14:35:27

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Oct 2020 17:14:37
User entered 'Day 6'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:53:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T22:52:27', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'c319d6dc-6cbd-441a-a345-7a78aedcf48b' User entered 'Yes (Y)'	System	28 Oct 2020 03:52:45
	System	28 Oct 2020 03:52:45

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:53:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T22:52:32', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'c319d6dc-6cbd-441a-a345-7a78aedcf48b' User entered '96.4'	System	28 Oct 2020 03:52:45
	System	28 Oct 2020 03:52:45

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T22:52:35', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'c319d6dc-6cbd-441a-a345-7a78aedcf48b' User entered 'Yes (Y)'	System	28 Oct 2020 03:52:45
	System	28 Oct 2020 03:52:45

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
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 'Medication taken listed in medication log' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 15:11:19
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 'Medication taken listed in medication log' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 20:13:04
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.' (Site from System).	System	28 Oct 2020 03:52:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T22:52:40', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'c319d6dc-6cbd-441a-a345-7a78aedcf48b'	System	28 Oct 2020 03:52:45
User entered '1'	System	28 Oct 2020 03:52:45

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:53:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T22:52:40', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'c319d6dc-6cbd-441a-a345-7a78aedcf48b' User entered '0'	System	28 Oct 2020 03:52:45
	System	28 Oct 2020 03:52:45

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T22:52:43', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'c319d6dc-6cbd-441a-a345-7a78aedcf48b' User entered '27 Oct 2020 22:52'	System	28 Oct 2020 03:52:45
	System	28 Oct 2020 03:52:45

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Oct 2020 17:14:37
User entered 'Day 7'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:53:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-28T19:24:33', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '8995734c-425b-4f5c-9155-ba869e5ddfa1' User entered 'Yes (Y)'	System	29 Oct 2020 00:24:46
	System	29 Oct 2020 00:24:46

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:53:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-28T19:24:37', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '8995734c-425b-4f5c-9155-ba869e5ddfa1' User entered '96.8'	System	29 Oct 2020 00:24:46
	System	29 Oct 2020 00:24:46

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-28T19:24:40', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '8995734c-425b-4f5c-9155-ba869e5ddfa1' User entered 'No (N)'	System	29 Oct 2020 00:24:46
	System	29 Oct 2020 00:24:46

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-28T19:24:43', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '8995734c-425b-4f5c-9155-ba869e5ddfa1' User entered '28 Oct 2020 19:24'	System	29 Oct 2020 00:24:46
	System	29 Oct 2020 00:24:46

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Oct 2020 17:14:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T12:38:09', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '385bc9fc-01e0-4d63-8936-6df465909c0a'	System	22 Oct 2020 17:38:29
User entered 'Does not interfere with activity (2)'	System	22 Oct 2020 17:38:29

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T12:38:16', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '385bc9fc-01e0-4d63-8936-6df465909c0a' User entered 'No (N)'	System	22 Oct 2020 17:38:29
	System	22 Oct 2020 17:38:29

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T12:38:18', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '385bc9fc-01e0-4d63-8936-6df465909c0a' User entered 'No (N)'	System	22 Oct 2020 17:38:29
	System	22 Oct 2020 17:38:29

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T12:38:25', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '385bc9fc-01e0-4d63-8936-6df465909c0a' User entered 'None (1)'	System	22 Oct 2020 17:38:29
	System	22 Oct 2020 17:38:29

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T12:38:27', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '385bc9fc-01e0-4d63-8936-6df465909c0a' User entered '22 Oct 2020 12:38'	System	22 Oct 2020 17:38:29
	System	22 Oct 2020 17:38:29

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '22 Oct 2020 12:29'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '22 Oct 2020 14:59'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Oct 2020 17:14:37
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T19:12:58', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '10ba100b-e9e0-4b72-a607-14afa2bd8349'	System	23 Oct 2020 00:13:16
User entered 'Does not interfere with activity (2)'	System	23 Oct 2020 00:13:16

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T19:13:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '10ba100b-e9e0-4b72-a607-14afa2bd8349' User entered 'No (N)'	System	23 Oct 2020 00:13:16
	System	23 Oct 2020 00:13:16

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T19:13:10', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '10ba100b-e9e0-4b72-a607-14afa2bd8349' User entered 'No (N)'	System	23 Oct 2020 00:13:16
	System	23 Oct 2020 00:13:16

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T19:13:11', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '10ba100b-e9e0-4b72-a607-14afa2bd8349'	System	23 Oct 2020 00:13:16
User entered 'None (1)'	System	23 Oct 2020 00:13:16

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T19:13:14', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '10ba100b-e9e0-4b72-a607-14afa2bd8349' User entered '22 Oct 2020 19:13'	System	23 Oct 2020 00:13:16
	System	23 Oct 2020 00:13:16

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '22 Oct 2020 15:54'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Oct 2020 17:14:37
User entered 'Day 2'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-23T20:30:33', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9f409fd2-aa5b-43ca-bf79-d78aec0ad754'	System	24 Oct 2020 01:30:43
User entered 'None (1)'	System	24 Oct 2020 01:30:43

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-23T20:30:36', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9f409fd2-aa5b-43ca-bf79-d78aec0ad754'	System	24 Oct 2020 01:30:43
User entered 'No (N)'	System	24 Oct 2020 01:30:43

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-23T20:30:38', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9f409fd2-aa5b-43ca-bf79-d78aec0ad754'	System	24 Oct 2020 01:30:43
User entered 'No (N)'	System	24 Oct 2020 01:30:43

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-23T20:30:39', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9f409fd2-aa5b-43ca-bf79-d78aec0ad754'	System	24 Oct 2020 01:30:43
User entered 'None (1)'	System	24 Oct 2020 01:30:43

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-23T20:30:42', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9f409fd2-aa5b-43ca-bf79-d78aec0ad754' User entered '23 Oct 2020 20:30'	System	24 Oct 2020 01:30:43
	System	24 Oct 2020 01:30:43

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Oct 2020 17:14:37
User entered 'Day 3'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-24T16:22:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9ac382b4-acd6-44ee-88fd-eb0a67c57fa1'	System	24 Oct 2020 21:22:10
User entered 'None (1)'	System	24 Oct 2020 21:22:10

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-24T16:22:03', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9ac382b4-acd6-44ee-88fd-eb0a67c57fa1'	System	24 Oct 2020 21:22:10
User entered 'No (N)'	System	24 Oct 2020 21:22:10

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-24T16:22:05', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9ac382b4-acd6-44ee-88fd-eb0a67c57fa1' User entered 'No (N)'	System	24 Oct 2020 21:22:10
	System	24 Oct 2020 21:22:10

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-24T16:22:06', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9ac382b4-acd6-44ee-88fd-eb0a67c57fa1'	System	24 Oct 2020 21:22:10
User entered 'None (1)'	System	24 Oct 2020 21:22:10

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-24T16:22:08', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9ac382b4-acd6-44ee-88fd-eb0a67c57fa1' User entered '24 Oct 2020 16:22'	System	24 Oct 2020 21:22:10
	System	24 Oct 2020 21:22:10

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Oct 2020 17:14:37
User entered 'Day 4'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-25T18:35:09', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'eba74fcf-972c-493c-9617-00273d067ad2'	System	25 Oct 2020 23:35:21
User entered 'None (1)'	System	25 Oct 2020 23:35:21

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-25T18:35:11', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'eba74fcf-972c-493c-9617-00273d067ad2'	System	25 Oct 2020 23:35:21
User entered 'No (N)'	System	25 Oct 2020 23:35:21

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-25T18:35:12', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'eba74fcf-972c-493c-9617-00273d067ad2'	System	25 Oct 2020 23:35:21
User entered 'No (N)'	System	25 Oct 2020 23:35:21

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-25T18:35:13', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'eba74fcf-972c-493c-9617-00273d067ad2'	System	25 Oct 2020 23:35:21
User entered 'None (1)'	System	25 Oct 2020 23:35:21

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-25T18:35:17', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'eba74fcf-972c-493c-9617-00273d067ad2' User entered '25 Oct 2020 18:35'	System	25 Oct 2020 23:35:21
	System	25 Oct 2020 23:35:21

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Oct 2020 17:14:37
User entered 'Day 5'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T09:35:26', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '1f01ed4c-479f-405b-92fa-baa69da17d7b'	System	27 Oct 2020 14:35:37
User entered 'None (1)'	System	27 Oct 2020 14:35:37

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T09:35:29', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '1f01ed4c-479f-405b-92fa-baa69da17d7b' User entered 'No (N)'	System	27 Oct 2020 14:35:37
	System	27 Oct 2020 14:35:37

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T09:35:30', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '1f01ed4c-479f-405b-92fa-baa69da17d7b' User entered 'No (N)'	System	27 Oct 2020 14:35:37
	System	27 Oct 2020 14:35:37

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T09:35:31', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '1f01ed4c-479f-405b-92fa-baa69da17d7b'	System	27 Oct 2020 14:35:37
User entered 'None (1)'	System	27 Oct 2020 14:35:37

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T09:35:34', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '1f01ed4c-479f-405b-92fa-baa69da17d7b' User entered '27 Oct 2020 09:35'	System	27 Oct 2020 14:35:37
	System	27 Oct 2020 14:35:37

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Oct 2020 17:14:37
User entered 'Day 6'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T22:52:47', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '4e3ed58e-3ba4-45ba-8c26-656ef8866e56'	System	28 Oct 2020 03:52:56
User entered 'None (1)'	System	28 Oct 2020 03:52:56

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T22:52:49', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '4e3ed58e-3ba4-45ba-8c26-656ef8866e56' User entered 'No (N)'	System	28 Oct 2020 03:52:56
	System	28 Oct 2020 03:52:56

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T22:52:51', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '4e3ed58e-3ba4-45ba-8c26-656ef8866e56' User entered 'No (N)'	System	28 Oct 2020 03:52:56
	System	28 Oct 2020 03:52:56

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T22:52:52', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '4e3ed58e-3ba4-45ba-8c26-656ef8866e56'	System	28 Oct 2020 03:52:56
User entered 'None (1)'	System	28 Oct 2020 03:52:56

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T22:52:54', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '4e3ed58e-3ba4-45ba-8c26-656ef8866e56' User entered '27 Oct 2020 22:52'	System	28 Oct 2020 03:52:56
	System	28 Oct 2020 03:52:56

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Oct 2020 17:14:37
User entered 'Day 7'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-28T19:24:46', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'c33a487f-22f0-4471-b6d1-05e3cbd5c6c0'	System	29 Oct 2020 00:24:57
User entered 'None (1)'	System	29 Oct 2020 00:24:57

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-28T19:24:48', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'c33a487f-22f0-4471-b6d1-05e3cbd5c6c0'	System	29 Oct 2020 00:24:57
User entered 'No (N)'	System	29 Oct 2020 00:24:57

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-28T19:24:50', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'c33a487f-22f0-4471-b6d1-05e3cbd5c6c0'	System	29 Oct 2020 00:24:57
User entered 'No (N)'	System	29 Oct 2020 00:24:57

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-28T19:24:51', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'c33a487f-22f0-4471-b6d1-05e3cbd5c6c0'	System	29 Oct 2020 00:24:57
User entered 'None (1)'	System	29 Oct 2020 00:24:57

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:53:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-28T19:24:53', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'c33a487f-22f0-4471-b6d1-05e3cbd5c6c0' User entered '28 Oct 2020 19:24'	System	29 Oct 2020 00:24:57
	System	29 Oct 2020 00:24:57

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Oct 2020 17:14:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T12:38:37', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '0732752a-906c-4ca5-b5a3-540ee9401f25' User entered 'None (0)'	System	22 Oct 2020 17:38:53
	System	22 Oct 2020 17:38:53

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T12:38:39', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '0732752a-906c-4ca5-b5a3-540ee9401f25' User entered 'None (0)'	System	22 Oct 2020 17:38:53
	System	22 Oct 2020 17:38:53

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T12:38:41', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '0732752a-906c-4ca5-b5a3-540ee9401f25' User entered 'None (0)'	System	22 Oct 2020 17:38:53
	System	22 Oct 2020 17:38:53

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T12:38:42', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '0732752a-906c-4ca5-b5a3-540ee9401f25' User entered 'None (0)'	System	22 Oct 2020 17:38:53
	System	22 Oct 2020 17:38:53

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T12:38:44', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '0732752a-906c-4ca5-b5a3-540ee9401f25' User entered 'None (0)'	System	22 Oct 2020 17:38:53
	System	22 Oct 2020 17:38:53

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T12:38:45', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '0732752a-906c-4ca5-b5a3-540ee9401f25' User entered 'None (0)'	System	22 Oct 2020 17:38:53
	System	22 Oct 2020 17:38:53

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T12:38:49', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '0732752a-906c-4ca5-b5a3-540ee9401f25' User entered 'No (N)'	System	22 Oct 2020 17:38:53
	System	22 Oct 2020 17:38:53

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T12:38:51', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '0732752a-906c-4ca5-b5a3-540ee9401f25' User entered '22 Oct 2020 12:38'	System	22 Oct 2020 17:38:53
	System	22 Oct 2020 17:38:53

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '22 Oct 2020 12:29'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '22 Oct 2020 14:59'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Oct 2020 17:14:37
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T19:13:34', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '27022c59-4460-46cd-a8a8-af6a50885831' User entered 'None (0)'	System	23 Oct 2020 00:14:18
	System	23 Oct 2020 00:14:18

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T19:13:35', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '27022c59-4460-46cd-a8a8-af6a50885831' User entered 'None (0)'	System	23 Oct 2020 00:14:18
	System	23 Oct 2020 00:14:18

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T19:13:39', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '27022c59-4460-46cd-a8a8-af6a50885831' User entered 'None (0)'	System	23 Oct 2020 00:14:18
	System	23 Oct 2020 00:14:18

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T19:13:40', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '27022c59-4460-46cd-a8a8-af6a50885831' User entered 'None (0)'	System	23 Oct 2020 00:14:18
	System	23 Oct 2020 00:14:18

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T19:13:42', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '27022c59-4460-46cd-a8a8-af6a50885831' User entered 'None (0)'	System	23 Oct 2020 00:14:18
	System	23 Oct 2020 00:14:18

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T19:13:43', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '27022c59-4460-46cd-a8a8-af6a50885831' User entered 'None (0)'	System	23 Oct 2020 00:14:18
	System	23 Oct 2020 00:14:18

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T19:14:13', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '27022c59-4460-46cd-a8a8-af6a50885831' User entered 'No (N)'	System	23 Oct 2020 00:14:18
	System	23 Oct 2020 00:14:18

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-22T19:14:15', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '27022c59-4460-46cd-a8a8-af6a50885831' User entered '22 Oct 2020 19:14'	System	23 Oct 2020 00:14:18
	System	23 Oct 2020 00:14:18

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '22 Oct 2020 15:54'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Oct 2020 17:14:37
User entered 'Day 2'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-23T20:30:47', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '07055b83-c977-4ecb-a23f-3a42be5c580b' User entered 'None (0)'	System	24 Oct 2020 01:31:04
	System	24 Oct 2020 01:31:04

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-23T20:30:49', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '07055b83-c977-4ecb-a23f-3a42be5c580b' User entered 'None (0)'	System	24 Oct 2020 01:31:04
	System	24 Oct 2020 01:31:04

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-23T20:30:51', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '07055b83-c977-4ecb-a23f-3a42be5c580b' User entered 'None (0)'	System	24 Oct 2020 01:31:04
	System	24 Oct 2020 01:31:04

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-23T20:30:52', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '07055b83-c977-4ecb-a23f-3a42be5c580b' User entered 'None (0)'	System	24 Oct 2020 01:31:04
	System	24 Oct 2020 01:31:04

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-23T20:30:54', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '07055b83-c977-4ecb-a23f-3a42be5c580b' User entered 'None (0)'	System	24 Oct 2020 01:31:04
	System	24 Oct 2020 01:31:04

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-23T20:30:55', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '07055b83-c977-4ecb-a23f-3a42be5c580b' User entered 'None (0)'	System	24 Oct 2020 01:31:04
	System	24 Oct 2020 01:31:04

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-23T20:30:57', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '07055b83-c977-4ecb-a23f-3a42be5c580b'	System	24 Oct 2020 01:31:04
User entered 'No (N)'	System	24 Oct 2020 01:31:04

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-23T20:30:59', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '07055b83-c977-4ecb-a23f-3a42be5c580b' User entered '23 Oct 2020 20:30'	System	24 Oct 2020 01:31:04
	System	24 Oct 2020 01:31:04

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Oct 2020 17:14:37
User entered 'Day 3'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-24T16:22:11', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9efd591c-7279-4f85-99a2-4035a7714a2a' User entered 'None (0)'	System	24 Oct 2020 21:22:24
	System	24 Oct 2020 21:22:24

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-24T16:22:13', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9efd591c-7279-4f85-99a2-4035a7714a2a' User entered 'None (0)'	System	24 Oct 2020 21:22:24
	System	24 Oct 2020 21:22:24

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-24T16:22:14', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9efd591c-7279-4f85-99a2-4035a7714a2a' User entered 'None (0)'	System	24 Oct 2020 21:22:24
	System	24 Oct 2020 21:22:24

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-24T16:22:15', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9efd591c-7279-4f85-99a2-4035a7714a2a' User entered 'None (0)'	System	24 Oct 2020 21:22:24
	System	24 Oct 2020 21:22:24

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-24T16:22:17', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9efd591c-7279-4f85-99a2-4035a7714a2a' User entered 'None (0)'	System	24 Oct 2020 21:22:24
	System	24 Oct 2020 21:22:24

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-24T16:22:18', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9efd591c-7279-4f85-99a2-4035a7714a2a' User entered 'None (0)'	System	24 Oct 2020 21:22:24
	System	24 Oct 2020 21:22:24

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-24T16:22:20', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9efd591c-7279-4f85-99a2-4035a7714a2a' User entered 'No (N)'	System	24 Oct 2020 21:22:24
	System	24 Oct 2020 21:22:24

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-24T16:22:22', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '9efd591c-7279-4f85-99a2-4035a7714a2a' User entered '24 Oct 2020 16:22'	System	24 Oct 2020 21:22:24
	System	24 Oct 2020 21:22:24

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Oct 2020 17:14:37
User entered 'Day 4'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-25T18:35:23', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '435d01c8-3300-4066-98b9-ff374d525b03' User entered 'None (0)'	System	25 Oct 2020 23:35:37
	System	25 Oct 2020 23:35:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-25T18:35:24', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '435d01c8-3300-4066-98b9-ff374d525b03' User entered 'None (0)'	System	25 Oct 2020 23:35:37
	System	25 Oct 2020 23:35:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-25T18:35:26', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '435d01c8-3300-4066-98b9-ff374d525b03' User entered 'None (0)'	System	25 Oct 2020 23:35:37
	System	25 Oct 2020 23:35:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-25T18:35:27', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '435d01c8-3300-4066-98b9-ff374d525b03' User entered 'None (0)'	System	25 Oct 2020 23:35:37
	System	25 Oct 2020 23:35:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-25T18:35:28', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '435d01c8-3300-4066-98b9-ff374d525b03' User entered 'None (0)'	System	25 Oct 2020 23:35:37
	System	25 Oct 2020 23:35:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-25T18:35:29', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '435d01c8-3300-4066-98b9-ff374d525b03' User entered 'None (0)'	System	25 Oct 2020 23:35:37
	System	25 Oct 2020 23:35:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-25T18:35:31', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '435d01c8-3300-4066-98b9-ff374d525b03' User entered 'No (N)'	System	25 Oct 2020 23:35:37
	System	25 Oct 2020 23:35:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-25T18:35:33', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '435d01c8-3300-4066-98b9-ff374d525b03' User entered '25 Oct 2020 18:35'	System	25 Oct 2020 23:35:37
	System	25 Oct 2020 23:35:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Oct 2020 17:14:37
User entered 'Day 5'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T09:35:40', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'b45595b9-5900-4ea2-a3f1-c2c538e6396d' User entered 'None (0)'	System	27 Oct 2020 14:35:52
	System	27 Oct 2020 14:35:52

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T09:35:41', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'b45595b9-5900-4ea2-a3f1-c2c538e6396d' User entered 'None (0)'	System	27 Oct 2020 14:35:52
	System	27 Oct 2020 14:35:52

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T09:35:42', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'b45595b9-5900-4ea2-a3f1-c2c538e6396d' User entered 'None (0)'	System	27 Oct 2020 14:35:52
	System	27 Oct 2020 14:35:52

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T09:35:43', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'b45595b9-5900-4ea2-a3f1-c2c538e6396d' User entered 'None (0)'	System	27 Oct 2020 14:35:52
	System	27 Oct 2020 14:35:52

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T09:35:44', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'b45595b9-5900-4ea2-a3f1-c2c538e6396d' User entered 'None (0)'	System	27 Oct 2020 14:35:52
	System	27 Oct 2020 14:35:52

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T09:35:46', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'b45595b9-5900-4ea2-a3f1-c2c538e6396d' User entered 'None (0)'	System	27 Oct 2020 14:35:52
	System	27 Oct 2020 14:35:52

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T09:35:48', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'b45595b9-5900-4ea2-a3f1-c2c538e6396d' User entered 'No (N)'	System	27 Oct 2020 14:35:52
	System	27 Oct 2020 14:35:52

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T09:35:51', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'b45595b9-5900-4ea2-a3f1-c2c538e6396d' User entered '27 Oct 2020 09:35'	System	27 Oct 2020 14:35:52
	System	27 Oct 2020 14:35:52

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Oct 2020 17:14:37
User entered 'Day 6'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T22:53:47', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'c614a549-8207-453f-9641-b10e21af7994'	System	28 Oct 2020 03:53:54
User entered 'No interference with activity (1)'	System	28 Oct 2020 03:53:54

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T22:53:19', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'c614a549-8207-453f-9641-b10e21af7994' User entered 'None (0)'	System	28 Oct 2020 03:53:54
	System	28 Oct 2020 03:53:54

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T22:53:21', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'c614a549-8207-453f-9641-b10e21af7994'	System	28 Oct 2020 03:53:54
User entered 'None (0)'	System	28 Oct 2020 03:53:54

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T22:53:22', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'c614a549-8207-453f-9641-b10e21af7994' User entered 'None (0)'	System	28 Oct 2020 03:53:54
	System	28 Oct 2020 03:53:54

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T22:53:23', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'c614a549-8207-453f-9641-b10e21af7994'	System	28 Oct 2020 03:53:54
User entered 'None (0)'	System	28 Oct 2020 03:53:54

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T22:53:25', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'c614a549-8207-453f-9641-b10e21af7994' User entered 'None (0)'	System	28 Oct 2020 03:53:54
	System	28 Oct 2020 03:53:54

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T22:53:27', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'c614a549-8207-453f-9641-b10e21af7994'	System	28 Oct 2020 03:53:54
User entered 'No (N)'	System	28 Oct 2020 03:53:54

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-27T22:53:50', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'c614a549-8207-453f-9641-b10e21af7994' User entered '27 Oct 2020 22:53'	System	28 Oct 2020 03:53:54
	System	28 Oct 2020 03:53:54

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
Data entry locked.	System	22 Oct 2020 17:14:37
User entered 'Day 7'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-28T19:24:58', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '19db0dc7-b706-45e3-a897-fca6fef08c7f' User entered 'None (0)'	System	29 Oct 2020 00:25:18
	System	29 Oct 2020 00:25:18

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-28T19:24:59', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '19db0dc7-b706-45e3-a897-fca6fef08c7f' User entered 'None (0)'	System	29 Oct 2020 00:25:18
	System	29 Oct 2020 00:25:18

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-28T19:25:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '19db0dc7-b706-45e3-a897-fca6fef08c7f' User entered 'None (0)'	System	29 Oct 2020 00:25:18
	System	29 Oct 2020 00:25:18

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-28T19:25:02', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '19db0dc7-b706-45e3-a897-fca6fef08c7f' User entered 'None (0)'	System	29 Oct 2020 00:25:18
	System	29 Oct 2020 00:25:18

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-28T19:25:03', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '19db0dc7-b706-45e3-a897-fca6fef08c7f' User entered 'None (0)'	System	29 Oct 2020 00:25:18
	System	29 Oct 2020 00:25:18

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-28T19:25:06', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '19db0dc7-b706-45e3-a897-fca6fef08c7f' User entered 'None (0)'	System	29 Oct 2020 00:25:18
	System	29 Oct 2020 00:25:18

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:02

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 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-28T19:25:13', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '19db0dc7-b706-45e3-a897-fca6fef08c7f' User entered 'No (N)'	System	29 Oct 2020 00:25:18
	System	29 Oct 2020 00:25:18

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-10-28T19:25:16', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '19db0dc7-b706-45e3-a897-fca6fef08c7f' User entered '28 Oct 2020 19:25'	System	29 Oct 2020 00:25:18
	System	29 Oct 2020 00:25:18

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 17:14:37

US3492228

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:52:37
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 17:14:37

US3492228

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	02 Nov 2020 20:03:20

US3492228

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '30 Oct 2020'	(b) (4) Lorna Sanchez McCann (b) (4)	02 Nov 2020 20:03:20

US3492228

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	(b) (4)	02 Nov 2020 20:04:31
User entered 'Contact Made (CONTACT MADE)'	Lorna Sanchez McCann (b) (4)	02 Nov 2020 20:03:20

US3492228

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '3 call attempts made, no contact with participant. proxy contact information contained a wrong phone number.' reason for change: Data Entry Error	(b) (4)	02 Nov 2020 20:04:31
User entered empty.	Lorna Sanchez McCann (b) (4)	02 Nov 2020 20:03:20

US3492228

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	04 Nov 2020 15:13:48

US3492228

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered '1'	System	04 Nov 2020 15:13:48

US3492228

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:44:14

US3492228

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '5 Nov 2020'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:44:14

US3492228

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:44:14

US3492228

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:44:14

US3492228

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:44:21

US3492228

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered '1'	System	06 Nov 2020 14:44:21

US3492228

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	16 Nov 2020 18:29:16

US3492228

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '13 Nov 2020'	(b) (4) Lorna Sanchez McCann (b) (4)	16 Nov 2020 18:29:16

US3492228

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lorna Sanchez McCann (b) (4)	16 Nov 2020 18:29:16

US3492228

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered empty.	(b) (4) Lorna Sanchez McCann (b) (4)	16 Nov 2020 18:29:16

US3492228

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	16 Nov 2020 18:29:45

US3492228

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered '1'	System	16 Nov 2020 18:29:45

US3492228

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:33:47

US3492228

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '17 Nov 2020'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:33:47

US3492228

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:33:47

US3492228

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered 'VISIT3'	System	17 Nov 2020 19:33:47

US3492228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:34:40

US3492228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '17 Nov 2020'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:34:40

US3492228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '13:20'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:34:40

US3492228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered '17 Nov 2020 13:20'	System	17 Nov 2020 19:34:40

US3492228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:34:40

US3492228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:34:40

US3492228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'tympanic'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:34:40

US3492228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '69'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:34:40

US3492228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered 'bpm'	System	17 Nov 2020 19:34:40

US3492228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '14'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:34:40

US3492228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered 'breaths/min'	System	17 Nov 2020 19:34:40

US3492228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '107'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:34:40

US3492228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered 'mmHg'	System	17 Nov 2020 19:34:40

US3492228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '72'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:34:40

US3492228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered 'mmHg'	System	17 Nov 2020 19:34:40

US3492228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56

US3492228

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56

US3492228

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:34:02

US3492228

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '17 Nov 2020'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:34:02

US3492228

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:39:18

US3492228

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '17 Nov 2020'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:39:18

US3492228

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered '13:35'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:39:18

US3492228

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered '17 Nov 2020 13:35'	System	17 Nov 2020 19:39:18

US3492228

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:35:04

US3492228

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered '1'	System	17 Nov 2020 19:35:04

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-11-22T00:02:39', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '32f8b22d-8029-41d5-a2e5-2b0e60643f06'	System	22 Nov 2020 06:03:34
User entered 'No (N)'	System	22 Nov 2020 06:03:34

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

Have you been exposed to someone with 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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-11-22T00:03:21', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '32f8b22d-8029-41d5-a2e5-2b0e60643f06' User entered 'No (N)'	System	22 Nov 2020 06:03:34
	System	22 Nov 2020 06:03:34

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-11-22T00:03:30', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '32f8b22d-8029-41d5-a2e5-2b0e60643f06' User entered '22 Nov 2020 00:03:30'	System	22 Nov 2020 06:03:34
	System	22 Nov 2020 06:03:34

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-11-28T21:29:34', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '5edc1d4b-9a6a-483d-aac2-6b1086f99b41'	System	29 Nov 2020 03:29:45
User entered 'No (N)'	System	29 Nov 2020 03:29:45

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

Have you been exposed to someone with 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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-11-28T21:29:40', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '5edc1d4b-9a6a-483d-aac2-6b1086f99b41'	System	29 Nov 2020 03:29:45
User entered 'No (N)'	System	29 Nov 2020 03:29:45

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-11-28T21:29:43', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '5edc1d4b-9a6a-483d-aac2-6b1086f99b41' User entered '28 Nov 2020 21:29:43'	System	29 Nov 2020 03:29:45

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-12-03T10:26:36', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '1b873ebc-aa26-4d31-8e45-d87fbf09cf63'	System	03 Dec 2020 16:26:45
User entered 'No (N)'	System	03 Dec 2020 16:26:45

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

Have you been exposed to someone with 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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-12-03T10:26:39', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '1b873ebc-aa26-4d31-8e45-d87fbf09cf63'	System	03 Dec 2020 16:26:45
User entered 'No (N)'	System	03 Dec 2020 16:26:45

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-12-03T10:26:42', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '1b873ebc-aa26-4d31-8e45-d87fbf09cf63' User entered '03 Dec 2020 10:26:42'	System	03 Dec 2020 16:26:45
	System	03 Dec 2020 16:26:45

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-12-12T12:24:12', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'eaa67916-4b4a-45ec-8e73-f08f4d2ea152'	System	12 Dec 2020 18:24:21
User entered 'No (N)'	System	12 Dec 2020 18:24:21

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

Have you been exposed to someone with 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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-12-12T12:24:16', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'eaa67916-4b4a-45ec-8e73-f08f4d2ea152'	System	12 Dec 2020 18:24:21
User entered 'No (N)'	System	12 Dec 2020 18:24:21

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-12-12T12:24:19', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'eaa67916-4b4a-45ec-8e73-f08f4d2ea152' User entered '12 Dec 2020 12:24:19'	System	12 Dec 2020 18:24:21
	System	12 Dec 2020 18:24:21

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-12-19T09:12:25', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'a3744011-3a81-4d42-bc6d-6f88cba1a565'	System	19 Dec 2020 15:12:33
User entered 'No (N)'	System	19 Dec 2020 15:12:33

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

Have you been exposed to someone with 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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-12-19T09:12:27', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'a3744011-3a81-4d42-bc6d-6f88cba1a565'	System	19 Dec 2020 15:12:33
User entered 'No (N)'	System	19 Dec 2020 15:12:33

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-12-19T09:12:30', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'a3744011-3a81-4d42-bc6d-6f88cba1a565' User entered '19 Dec 2020 09:12:30'	System	19 Dec 2020 15:12:33
	System	19 Dec 2020 15:12:33

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-12-26T12:03:41', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'f2d7eef5-edfd-49df-b65e-1f7a2fb41b24'	System	26 Dec 2020 17:03:50
User entered 'No (N)'	System	26 Dec 2020 17:03:50

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

Have you been exposed to someone with 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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-12-26T12:03:44', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'f2d7eef5-edfd-49df-b65e-1f7a2fb41b24'	System	26 Dec 2020 17:03:50
User entered 'No (N)'	System	26 Dec 2020 17:03:50

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-12-26T12:03:47', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'f2d7eef5-edfd-49df-b65e-1f7a2fb41b24'	System	26 Dec 2020 17:03:50
User entered '26 Dec 2020 12:03:47'	System	26 Dec 2020 17:03:50

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-12-31T07:22:22', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'ca7e917d-e828-45ef-a214-b895205409cc'	System	31 Dec 2020 13:22:36
User entered 'No (N)'	System	31 Dec 2020 13:22:36

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

Have you been exposed to someone with 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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-12-31T07:22:29', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'ca7e917d-e828-45ef-a214-b895205409cc' User entered 'No (N)'	System	31 Dec 2020 13:22:36
	System	31 Dec 2020 13:22:36

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2020-12-31T07:22:33', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'ca7e917d-e828-45ef-a214-b895205409cc' User entered '31 Dec 2020 07:22:33'	System	31 Dec 2020 13:22:36
	System	31 Dec 2020 13:22:36

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-01-09T12:09:09', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'fbd44d39-a4d3-48ef-b8e0-238687f5e4d4'	System	09 Jan 2021 20:09:16
User entered 'No (N)'	System	09 Jan 2021 20:09:16

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

Have you been exposed to someone with 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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-01-09T12:09:11', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'fbd44d39-a4d3-48ef-b8e0-238687f5e4d4'	System	09 Jan 2021 20:09:16
User entered 'No (N)'	System	09 Jan 2021 20:09:16

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-01-09T12:09:13', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'fbd44d39-a4d3-48ef-b8e0-238687f5e4d4' User entered '09 Jan 2021 12:09:13'	System	09 Jan 2021 20:09:16
	System	09 Jan 2021 20:09:16

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-01-14T07:51:37', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'fc2949a7-9391-40bb-be71-a91a4c001c3c'	System	14 Jan 2021 13:51:48
User entered 'No (N)'	System	14 Jan 2021 13:51:48

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

Have you been exposed to someone with 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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-01-14T07:51:41', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'fc2949a7-9391-40bb-be71-a91a4c001c3c' User entered 'No (N)'	System	14 Jan 2021 13:51:48
	System	14 Jan 2021 13:51:48

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-01-14T07:51:44', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'fc2949a7-9391-40bb-be71-a91a4c001c3c'	System	14 Jan 2021 13:51:48
User entered '14 Jan 2021 07:51:44'	System	14 Jan 2021 13:51:48

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-01-23T12:25:07', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'b1835318-c554-4e72-b5eb-c438ba26ea92'	System	23 Jan 2021 18:25:22
User entered 'No (N)'	System	23 Jan 2021 18:25:22

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

Have you been exposed to someone with 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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-01-23T12:25:09', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'b1835318-c554-4e72-b5eb-c438ba26ea92'	System	23 Jan 2021 18:25:22
User entered 'No (N)'	System	23 Jan 2021 18:25:22

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-01-23T12:25:19', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'b1835318-c554-4e72-b5eb-c438ba26ea92'	System	23 Jan 2021 18:25:22
User entered '23 Jan 2021 12:25:19'	System	23 Jan 2021 18:25:22

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-01-28T09:06:49', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '0b0e599d-ff62-4bd1-a877-8e6e910e522d'	System	28 Jan 2021 15:07:07
User entered 'No (N)'	System	28 Jan 2021 15:07:07

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

Have you been exposed to someone with 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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-01-28T09:06:53', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '0b0e599d-ff62-4bd1-a877-8e6e910e522d' User entered 'No (N)'	System	28 Jan 2021 15:07:07
	System	28 Jan 2021 15:07:07

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-01-28T09:07:05', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '0b0e599d-ff62-4bd1-a877-8e6e910e522d' User entered '28 Jan 2021 09:07:05'	System	28 Jan 2021 15:07:07
	System	28 Jan 2021 15:07:07

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-02-07T18:00:31', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '88b365cf-7222-4d7f-9f34-eda580c6a5cf'	System	08 Feb 2021 00:00:58
User entered 'No (N)'	System	08 Feb 2021 00:00:58

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

Have you been exposed to someone with 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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-02-07T18:00:34', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '88b365cf-7222-4d7f-9f34-eda580c6a5cf' User entered 'No (N)'	System	08 Feb 2021 00:00:58

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-02-07T18:00:36', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '88b365cf-7222-4d7f-9f34-eda580c6a5cf' User entered '07 Feb 2021 18:00:36'	System	08 Feb 2021 00:00:58
	System	08 Feb 2021 00:00:58

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-02-13T19:14:21', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'a490b55d-974c-4328-b0e3-81337313828a'	System	14 Feb 2021 01:14:31
User entered 'No (N)'	System	14 Feb 2021 01:14:31

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

Have you been exposed to someone with 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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-02-13T19:14:24', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'a490b55d-974c-4328-b0e3-81337313828a'	System	14 Feb 2021 01:14:31
User entered 'No (N)'	System	14 Feb 2021 01:14:31

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-02-13T19:14:26', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'a490b55d-974c-4328-b0e3-81337313828a'	System	14 Feb 2021 01:14:31
User entered '13 Feb 2021 19:14:26'	System	14 Feb 2021 01:14:31

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-02-21T18:29:55', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '7c8b07bf-6d98-49d5-9fdb-34170524098d'	System	22 Feb 2021 00:30:03
User entered 'No (N)'	System	22 Feb 2021 00:30:03

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

Have you been exposed to someone with 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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-02-21T18:29:58', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '7c8b07bf-6d98-49d5-9fdb-34170524098d'	System	22 Feb 2021 00:30:03
User entered 'No (N)'	System	22 Feb 2021 00:30:03

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-02-21T18:30:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '7c8b07bf-6d98-49d5-9fdb-34170524098d'	System	22 Feb 2021 00:30:03
User entered '21 Feb 2021 18:30:00'	System	22 Feb 2021 00:30:03

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-02-25T10:25:10', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '950c8d31-f15c-4b4f-b01c-16ec5ec4ec55'	System	26 Feb 2021 03:41:02
User entered 'No (N)'	System	26 Feb 2021 03:41:02

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

Have you been exposed to someone with 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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-02-25T10:25:02', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '950c8d31-f15c-4b4f-b01c-16ec5ec4ec55'	System	26 Feb 2021 03:41:02
User entered 'No (N)'	System	26 Feb 2021 03:41:02

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-02-25T10:25:16', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '950c8d31-f15c-4b4f-b01c-16ec5ec4ec55'	System	26 Feb 2021 03:41:02
User entered '25 Feb 2021 10:25:16'	System	26 Feb 2021 03:41:02

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-03-06T14:42:15', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '39771785-684f-40b3-bf95-7d3a4c152675'	System	06 Mar 2021 20:42:22
User entered 'No (N)'	System	06 Mar 2021 20:42:22

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

Have you been exposed to someone with 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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-03-06T14:42:17', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '39771785-684f-40b3-bf95-7d3a4c152675'	System	06 Mar 2021 20:42:22
User entered 'No (N)'	System	06 Mar 2021 20:42:22

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-03-06T14:42:20', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '39771785-684f-40b3-bf95-7d3a4c152675' User entered '06 Mar 2021 14:42:20'	System	06 Mar 2021 20:42:22
	System	06 Mar 2021 20:42:22

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-03-11T06:46:47', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '79a25277-90ef-4b67-a94c-59f9006aa24d'	System	11 Mar 2021 12:47:18
User entered 'Yes (Y)'	System	11 Mar 2021 12:47:18

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

Have you been exposed to someone with 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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-03-11T06:47:02', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '79a25277-90ef-4b67-a94c-59f9006aa24d'	System	11 Mar 2021 12:47:18
User entered 'No (N)'	System	11 Mar 2021 12:47:18

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-03-11T06:47:05', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '79a25277-90ef-4b67-a94c-59f9006aa24d'	System	11 Mar 2021 12:47:18
User entered 'No (N)'	System	11 Mar 2021 12:47:18

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-03-11T06:47:10', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '79a25277-90ef-4b67-a94c-59f9006aa24d'	System	11 Mar 2021 12:47:18
User entered 'No (N)'	System	11 Mar 2021 12:47:18

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-03-11T06:47:17', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '79a25277-90ef-4b67-a94c-59f9006aa24d' User entered '11 Mar 2021 06:47:17'	System	11 Mar 2021 12:47:18
	System	11 Mar 2021 12:47:18

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-03-19T19:06:53-05:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'f0236983-6659-4a4f-a350-e1fd83d3907d'	System	20 Mar 2021 00:07:02
User entered 'No (N)'	System	20 Mar 2021 00:07:02

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

Have you been exposed to someone with 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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-03-19T19:06:57-05:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'f0236983-6659-4a4f-a350-e1fd83d3907d'	System	20 Mar 2021 00:07:02
User entered 'No (N)'	System	20 Mar 2021 00:07:02

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-03-19T19:06:59-05:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'f0236983-6659-4a4f-a350-e1fd83d3907d' User entered '19 Mar 2021 19:06:59'	System	20 Mar 2021 00:07:02
	System	20 Mar 2021 00:07:02

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-03-27T12:11:08-05:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '2b9b46ce-fe58-457e-a0fb-2171613f59e1'	System	27 Mar 2021 17:11:17
User entered 'No (N)'	System	27 Mar 2021 17:11:17

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

Have you been exposed to someone with 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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-03-27T12:11:11-05:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '2b9b46ce-fe58-457e-a0fb-2171613f59e1'	System	27 Mar 2021 17:11:17
User entered 'No (N)'	System	27 Mar 2021 17:11:17

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-03-27T12:11:13-05:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '2b9b46ce-fe58-457e-a0fb-2171613f59e1'	System	27 Mar 2021 17:11:17
User entered '27 Mar 2021 12:11:13'	System	27 Mar 2021 17:11:17

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-04-01T11:34:25-05:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'b2fa6248-52dc-4b89-bacf-14922f2228d3'	System	01 Apr 2021 16:34:35
User entered 'No (N)'	System	01 Apr 2021 16:34:35

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

Have you been exposed to someone with 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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-04-01T11:34:27-05:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'b2fa6248-52dc-4b89-bacf-14922f2228d3'	System	01 Apr 2021 16:34:35
User entered 'No (N)'	System	01 Apr 2021 16:34:35

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-04-01T11:34:30-05:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'b2fa6248-52dc-4b89-bacf-14922f2228d3'	System	01 Apr 2021 16:34:35
User entered '01 Apr 2021 11:34:30'	System	01 Apr 2021 16:34:35

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-04-08T10:11:16-05:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'eacaa11b-c9c3-473a-bcef-2cd3f4634f64'	System	08 Apr 2021 15:11:30
User entered 'No (N)'	System	08 Apr 2021 15:11:30

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

Have you been exposed to someone with 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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-04-08T10:11:20-05:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'eacaa11b-c9c3-473a-bcef-2cd3f4634f64'	System	08 Apr 2021 15:11:30
User entered 'No (N)'	System	08 Apr 2021 15:11:30

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-04-08T10:11:24-05:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'eacaa11b-c9c3-473a-bcef-2cd3f4634f64'	System	08 Apr 2021 15:11:30
User entered '08 Apr 2021 10:11:24'	System	08 Apr 2021 15:11:30

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-04-16T13:07:49-05:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '51bfde9b-cceb-4358-a3f7-af692c506f75'	System	16 Apr 2021 18:07:58
User entered 'No (N)'	System	16 Apr 2021 18:07:58

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

Have you been exposed to someone with 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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-04-16T13:07:50-05:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '51bfde9b-cceb-4358-a3f7-af692c506f75'	System	16 Apr 2021 18:07:58
User entered 'No (N)'	System	16 Apr 2021 18:07:58

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-04-16T13:07:52-05:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '51bfde9b-cceb-4358-a3f7-af692c506f75' User entered '16 Apr 2021 13:07:52'	System	16 Apr 2021 18:07:58
	System	16 Apr 2021 18:07:58

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-04-24T12:00:26-05:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '376aedeb-bbf2-4c1a-b9d9-d0a6c637f0ba'	System	24 Apr 2021 17:00:43
User entered 'No (N)'	System	24 Apr 2021 17:00:43

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

Have you been exposed to someone with 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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-04-24T12:00:30-05:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '376aede8-bbf2-4c1a-b9d9-d0a6c637f0ba'	System	24 Apr 2021 17:00:43
User entered 'No (N)'	System	24 Apr 2021 17:00:43

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-04-24T12:00:32-05:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '376aedeb-bbf2-4c1a-b9d9-d0a6c637f0ba'	System	24 Apr 2021 17:00:43
User entered '24 Apr 2021 12:00:32'	System	24 Apr 2021 17:00:43

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-04-29T22:53:11-05:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '893c601f-a87d-431f-9a39-9a6edb2ce8f5'	System	30 Apr 2021 03:53:51
User entered 'No (N)'	System	30 Apr 2021 03:53:51

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

Have you been exposed to someone with 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 (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-04-29T22:53:13-05:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '893c601f-a87d-431f-9a39-9a6edb2ce8f5'	System	30 Apr 2021 03:53:51
User entered 'No (N)'	System	30 Apr 2021 03:53:51

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-04-29T22:53:15-05:00', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: '893c601f-a87d-431f-9a39-9a6edb2ce8f5'	System	30 Apr 2021 03:53:51
User entered '29 Apr 2021 22:53:15'	System	30 Apr 2021 03:53:51

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 10:08:09

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '17 Nov 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '21 Nov 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '24 Nov 2022 00:01'	System	20 Nov 2020 10:08:09

US3492228

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:08:09
Amendment Manager: User entered '28 Nov 2022 23:59'	System	20 Nov 2020 10:08:09

US3492228

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:53:02

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 13:26:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-03-06T14:42:43', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'a0de114c-dd5d-472a-ac33-a1a11eda52c6'	System	06 Mar 2021 20:42:50
User entered 'No (N)'	System	06 Mar 2021 20:42:50

US3492228

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:53:02

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:26:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AE783728-97E5-4D22-A3B0-465EC7EA80C2)', Time: '2021-03-06T14:42:46', User OID: 'PatientReportedOutcome (US3492228)', ODM File OID: 'a0de114c-dd5d-472a-ac33-a1a11eda52c6' User entered '06 Mar 2021 14:42:46'	System	06 Mar 2021 20:42:50
	System	06 Mar 2021 20:42:50

US3492228

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	16 Dec 2020 16:57:51

US3492228

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '16 Dec 2020'	Nia Moragne-O'Neal (b) (4)	16 Dec 2020 16:57:51

US3492228

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nia Moragne-O'Neal (b) (4)	16 Dec 2020 16:57:51

US3492228

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered empty.	(b) (4) Nia Moragne-O'Neal (b) (4)	16 Dec 2020 16:57:51

US3492228

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	16 Dec 2020 16:57:55

US3492228

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:41:56
User entered '1'	System	16 Dec 2020 16:57:55

US3492228

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:34
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	Ian Feather (b) (4)	22 Jan 2021 18:39:12

US3492228

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:34
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '22 Jan 2021'	(b) (4) Ian Feather (b) (4)	22 Jan 2021 18:39:12

US3492228

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:34
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Contact Made (CONTACT MADE)'	Ian Feather (b) (4)	22 Jan 2021 18:39:12

US3492228

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:34
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered empty.	Ian Feather (b) (4)	22 Jan 2021 18:39:12

US3492228

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:34
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	Ian Feather (b) (4)	22 Jan 2021 18:39:16

US3492228

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:34
User entered '1'	System	22 Jan 2021 18:39:16

US3492228

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'Yes (Y)'	Ian Feather (b) (4)	17 Feb 2021 18:04:18

US3492228

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered '17 Feb 2021'	Ian Feather (b) (4)	17 Feb 2021 18:04:18

US3492228

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'Contact Made (CONTACT MADE)'	Ian Feather (b) (4)	17 Feb 2021 18:04:18

US3492228

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered empty.	Ian Feather (b) (4)	17 Feb 2021 18:04:18

US3492228

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'Yes (Y)'	Ian Feather (b) (4)	17 Feb 2021 18:04:21

US3492228

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:34
User entered '1'	System	17 Feb 2021 18:04:21

US3492228

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 14:22:27

US3492228

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered '18 Mar 2021'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 14:22:27

US3492228

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 14:22:27

US3492228

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 14:22:27

US3492228

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:34
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 14:22:37

US3492228

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:40:34
User entered '1'	System	18 Mar 2021 14:22:37

US3492228

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:22
	(b) (4)	
User entered 'Yes (Y)'	Marla Schwarber (b) (4)	29 Apr 2021 16:09:06
	(b) (4)	

US3492228

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:22
	(b) (4)	
User entered '27 Apr 2021'	Marla Schwarber (b) (4)	29 Apr 2021 16:09:06
	(b) (4)	

US3492228

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:22
	(b) (4)	
User entered 'Clinic (Clinic)'	Marla Schwarber (b) (4)	29 Apr 2021 16:09:06
	(b) (4)	

US3492228

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	29 Apr 2021 16:09:06

US3492228

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:22
	(b) (4)	
User entered 'Yes (Y)'	Marla Schwarber (b) (4)	29 Apr 2021 16:10:01
	(b) (4)	

US3492228

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:22
	(b) (4)	
User entered '27 Apr 2021'	Marla Schwarber (b) (4)	29 Apr 2021 16:10:01
	(b) (4)	

US3492228

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:22
	(b) (4)	
User entered '09:02'	Marla Schwarber (b) (4)	29 Apr 2021 16:10:01
	(b) (4)	

US3492228

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
User entered '27 Apr 2021 09:02'	System	29 Apr 2021 16:10:01

US3492228

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). User signature succeeded.	(b) (4), (b) (6) [REDACTED]	01 May 2021 10:50:26
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:22
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	Marla Schwarber (b) (4) (b) (4)	29 Apr 2021 16:11:53
User entered '96.5' F	System Marla Schwarber (b) (4) (b) (4)	29 Apr 2021 16:10:01 29 Apr 2021 16:10:01

US3492228

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:22
	(b) (4)	
User entered 'Other (Other)'	Marla Schwarber (b) (4)	29 Apr 2021 16:10:01
	(b) (4)	

US3492228

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:22
	(b) (4)	
User entered 'tympanic'	Marla Schwarber (b) (4)	29 Apr 2021 16:10:01
	(b) (4)	

US3492228

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:22
	(b) (4)	
User entered '76'	Marla Schwarber (b) (4)	29 Apr 2021 16:10:01
	(b) (4)	

US3492228

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Apr 2021 16:10:01

US3492228

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:22
	(b) (4)	
User entered '16'	Marla Schwarber (b) (4)	29 Apr 2021 16:10:01
	(b) (4)	

US3492228

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Apr 2021 16:10:01

US3492228

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:22
	(b) (4)	
User entered '107'	Marla Schwarber (b) (4)	29 Apr 2021 16:10:01
	(b) (4)	

US3492228

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Apr 2021 16:10:01

US3492228

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:22
	(b) (4)	
User entered '67'	Marla Schwarber (b) (4)	29 Apr 2021 16:10:01
	(b) (4)	

US3492228

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Apr 2021 16:10:01

US3492228

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:22
	(b) (4)	
User entered 'Yes (Y)'	Marla Schwarber (b) (4)	29 Apr 2021 16:12:05
	(b) (4)	

US3492228

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:22
	(b) (4)	
User entered '27 Apr 2021'	Marla Schwarber (b) (4)	29 Apr 2021 16:12:05
	(b) (4)	

US3492228

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:22
	(b) (4)	
User entered 'Yes (Y)'	Marla Schwarber (b) (4)	29 Apr 2021 16:12:41
	(b) (4)	

US3492228

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:22
	(b) (4)	
User entered '27 Apr 2021'	Marla Schwarber (b) (4)	29 Apr 2021 16:12:41
	(b) (4)	

US3492228

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:22
	(b) (4)	
User entered '09:19'	Marla Schwarber (b) (4)	29 Apr 2021 16:12:41
	(b) (4)	

US3492228

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
User entered '27 Apr 2021 09:19'	System	29 Apr 2021 16:12:41

US3492228

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:22
	(b) (4)	
User entered 'Yes (Y)'	Marla Schwarber (b) (4)	29 Apr 2021 16:14:25
	(b) (4)	

US3492228

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 16:14:25

US3492228

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

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:33:09

US3492228

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

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '26 Jan 2021'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:33:09
	(b) (4)	

US3492228

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

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

[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 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Clinic (Clinic)'	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	26 Jan 2021 17:33:09

US3492228

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

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered 'UNBLND_DECIDE'	System	26 Jan 2021 17:33:09

US3492228

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:02

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '26 Jan 2021'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:33:22
	(b) (4)	

US3492228

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:02

[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 20:04:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered '0' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:50:24

US3492228

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:02

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:33:22

US3492228

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:02

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:50:24

US3492228

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:02

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '26 Jan 2021'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:33:22
	(b) (4)	

US3492228

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:02

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Placebo (Placebo)'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:33:22

US3492228

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:02

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Placebo (Placebo)'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:33:22
	(b) (4)	

US3492228

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:02

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Placebo (Placebo)'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:33:22

US3492228

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:02

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:33:22

US3492228

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:02

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered '1'	System	26 Jan 2021 17:33:22

US3492228

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:02

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered '1'	System	26 Jan 2021 17:33:22

US3492228

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered missing code ND - Not Done.	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered missing code ND - Not Done.	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:02

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered empty.	System	26 Jan 2021 17:34:30
DataPoint set to visible.	System	26 Jan 2021 17:33:22

US3492228

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered missing code ND - Not Done.	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered missing code ND - Not Done.	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:02

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered empty.	System	26 Jan 2021 17:34:30
DataPoint set to visible.	System	26 Jan 2021 17:33:22

US3492228

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User accepted default value 'Pre-Dose (PREDOSE)'	Gizelle Alvarez (b) (4) (b) (4)	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '26 Jan 2021'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:34:30
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '11:19'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered '26 Jan 2021 11:19'	System	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '97.6' F	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Other (Other)'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'tympanic'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:34:30
	(b) (4)	

US3492228

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '75'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered 'bpm'	System	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '16'	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered 'breaths/min'	System	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '105'	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered 'mmHg'	System	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '69'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered 'mmHg'	System	26 Jan 2021 17:34:30

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered missing code ND - Not Done.	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered missing code ND - Not Done.	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:02

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered empty.	System	26 Jan 2021 17:34:30
DataPoint set to visible.	System	26 Jan 2021 17:33:22

US3492228

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User accepted default value 'Post-Dose (POSTDOSE)'	Gizelle Alvarez (b) (4) (b) (4)	26 Jan 2021 17:34:30

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Marla Schwarber (b) (4)	26 Jan 2021 18:46:19
User entered 'No (N)'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered '26 Jan 2021' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	26 Jan 2021 18:46:19
User entered empty.	Gizelle Alvarez (b) (4) (b) (4)	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered '12:00' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	26 Jan 2021 18:46:19
User entered empty.	Gizelle Alvarez (b) (4) (b) (4)	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered '26 Jan 2021 12:00'	System	26 Jan 2021 18:46:19
User entered empty.	System	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered '97.6' F reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	26 Jan 2021 18:46:19
User entered empty.	Gizelle Alvarez (b) (4) (b) (4)	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered 'Other (Other)' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	26 Jan 2021 18:46:19
User entered empty.	Gizelle Alvarez (b) (4) (b) (4)	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'tympanic' reason for change: Data Entry Error	(b) (4) Marla Schwarber (b) (4)	26 Jan 2021 18:46:19
User entered empty.	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '66' reason for change: Data Entry Error	(b) (4)	
	Marla Schwarber (b) (4)	26 Jan 2021 18:46:19
User entered empty.	(b) (4)	
	Gizelle Alvarez (b) (4)	26 Jan 2021 17:34:30
	(b) (4)	

US3492228

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered 'bpm'	System	26 Jan 2021 18:46:19
User entered empty.	System	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered '16' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	26 Jan 2021 18:46:19
User entered empty.	Gizelle Alvarez (b) (4) (b) (4)	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered 'breaths/min'	System	26 Jan 2021 18:46:19
User entered empty.	System	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered '100' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	26 Jan 2021 18:46:19
User entered empty.	Gizelle Alvarez (b) (4) (b) (4)	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered 'mmHg'	System	26 Jan 2021 18:46:19
User entered empty.	System	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '65' reason for change: Data Entry Error	(b) (4) Marla Schwarber (b) (4)	26 Jan 2021 18:46:19
User entered empty.	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:34:30

US3492228

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered 'mmHg'	System	26 Jan 2021 18:46:19
User entered empty.	System	26 Jan 2021 17:34:30

US3492228

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:34:36

US3492228

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '26 Jan 2021'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:34:36
	(b) (4)	

US3492228

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:34:57

US3492228

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '26 Jan 2021'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:34:57

US3492228

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Urine (URINE)'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:34:57

US3492228

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Negative (NEGATIVE)'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:34:57

US3492228

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'No (N)'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:34:57
	(b) (4)	

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered empty.	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:34:57

US3492228

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered empty.	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:34:57
	(b) (4)	

US3492228

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered empty.	System	26 Jan 2021 17:34:57

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	26 Jan 2021 18:45:10

US3492228

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered empty.	Marla Schwarber (b) (4) (b) (4)	26 Jan 2021 18:45:10

US3492228

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

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 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered empty.	Marla Schwarber (b) (4) (b) (4)	26 Jan 2021 18:45:10

US3492228

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered 'mRNA-1273'	System	26 Jan 2021 18:45:10
DataPoint set to visible.	System	26 Jan 2021 17:33:22

US3492228

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '26 Jan 2021'	(b) (4) Marla Schwarber (b) (4)	26 Jan 2021 18:45:10

US3492228

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered '11:52'	Marla Schwarber (b) (4) (b) (4)	26 Jan 2021 18:45:10

US3492228

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered '26 Jan 2021 11:52'	System	26 Jan 2021 18:45:10

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Left Arm (LEFT ARM)'	(b) (4) Marla Schwarber (b) (4)	26 Jan 2021 18:45:10

US3492228

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered 'ONCE'	System	26 Jan 2021 18:45:10

US3492228

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered 'INTRAMUSCULAR'	System	26 Jan 2021 18:45:10

US3492228

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:35:11

US3492228

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '26 Jan 2021'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:35:11

US3492228

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '11:08'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:35:11

US3492228

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered '26 Jan 2021 11:08'	System	26 Jan 2021 17:35:11

US3492228

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:53:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:35:26

US3492228

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:53:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '26 Jan 2021'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:35:26

US3492228

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:53:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '11:15'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:35:26

US3492228

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered '26 Jan 2021 11:15'	System	26 Jan 2021 17:35:26

US3492228

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

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	(b) (4) Gizelle Alvarez (b) (4)	26 Jan 2021 17:35:30

US3492228

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

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:04:33
User entered '1'	System	26 Jan 2021 17:35:30

US3492228

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	Ian Feather (b) (4)	02 Feb 2021 15:59:50

US3492228

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '2 Feb 2021'	Ian Feather (b) (4)	02 Feb 2021 15:59:50

US3492228

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Contact Made (CONTACT MADE)'	Ian Feather (b) (4)	02 Feb 2021 15:59:50

US3492228

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered empty.	Ian Feather (b) (4)	02 Feb 2021 15:59:50

US3492228

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	Ian Feather (b) (4)	02 Feb 2021 15:59:54

US3492228

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User entered '1'	System	02 Feb 2021 15:59:54

US3492228

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User entered '1'	System	02 Feb 2021 15:59:54
DataPoint set to visible.	System	02 Feb 2021 15:59:54

US3492228

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	24 Feb 2021 15:20:12

US3492228

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered '24 Feb 2021'	(b) (4) Lorna Sanchez McCann (b) (4)	24 Feb 2021 15:20:12

US3492228

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'Clinic (Clinic)'	(b) (4) Lorna Sanchez McCann (b) (4)	24 Feb 2021 15:20:12

US3492228

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User entered 'OLD29'	System	24 Feb 2021 15:20:12

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User accepted default value 'Pre-Dose (PREDOSE)'	Lorna Sanchez McCann (b) (4)	24 Feb 2021 15:20:49

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	24 Feb 2021 15:20:49

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered '24 Feb 2021'	(b) (4) Lorna Sanchez McCann (b) (4)	24 Feb 2021 15:20:49

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered '09:01'	(b) (4) Lorna Sanchez McCann (b) (4)	24 Feb 2021 15:20:49

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User entered '24 Feb 2021 09:01'	System	24 Feb 2021 15:20:49

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:51:22
User entered '36.4' C	Lorna Sanchez McCann (b) (4)	24 Feb 2021 15:20:49

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'Other (Other)'	(b) (4) Lorna Sanchez McCann (b) (4)	24 Feb 2021 15:20:49

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:51:22
User entered 'tympanic'	Lorna Sanchez McCann (b) (4)	24 Feb 2021 15:20:49

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:51:22
User entered '66'	Lorna Sanchez McCann (b) (4)	24 Feb 2021 15:20:49

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User entered 'bpm'	System	24 Feb 2021 15:20:49

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:51:22
User entered '16'	Lorna Sanchez McCann (b) (4)	24 Feb 2021 15:20:49

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User entered 'breaths/min'	System	24 Feb 2021 15:20:49

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:51:22
User entered '113'	Lorna Sanchez McCann (b) (4)	24 Feb 2021 15:20:49

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User entered 'mmHg'	System	24 Feb 2021 15:20:49

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:51:22
User entered '76'	Lorna Sanchez McCann (b) (4)	24 Feb 2021 15:20:49

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User entered 'mmHg'	System	24 Feb 2021 15:20:49

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	24 Feb 2021 16:10:03

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:10:03

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:10:03

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered '10:06'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:10:03

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User entered '24 Feb 2021 10:06'	System	24 Feb 2021 16:10:03

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered '36.4' C	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:10:03

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:10:03

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'TMPANIC'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:10:03

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered '64'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:10:03

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User entered 'bpm'	System	24 Feb 2021 16:10:03

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered '16'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:10:03

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User entered 'breaths/min'	System	24 Feb 2021 16:10:03

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered '99'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:10:03

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User entered 'mmHg'	System	24 Feb 2021 16:10:03

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered '65'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:10:03

US3492228

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User entered 'mmHg'	System	24 Feb 2021 16:10:03

US3492228

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	24 Feb 2021 15:20:56

US3492228

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered '24 Feb 2021'	(b) (4) Lorna Sanchez McCann (b) (4)	24 Feb 2021 15:20:56

US3492228

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	24 Feb 2021 15:21:13

US3492228

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered '24 Feb 2021'	(b) (4) Lorna Sanchez McCann (b) (4)	24 Feb 2021 15:21:13

US3492228

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'Urine (URINE)'	(b) (4) Lorna Sanchez McCann (b) (4)	24 Feb 2021 15:21:13

US3492228

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'Negative (NEGATIVE)'	(b) (4) Lorna Sanchez McCann (b) (4)	24 Feb 2021 15:21:13

US3492228

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'No (N)'	(b) (4) Lorna Sanchez McCann (b) (4)	24 Feb 2021 15:21:13

US3492228

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:51:22
User entered empty.	Lorna Sanchez McCann (b) (4)	24 Feb 2021 15:21:13

US3492228

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:51:22
User entered empty.	Lorna Sanchez McCann (b) (4)	24 Feb 2021 15:21:13

US3492228

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User entered empty.	System	24 Feb 2021 15:21:13

US3492228

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:10:26

US3492228

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:10:26

US3492228

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:10:26

US3492228

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User entered 'mRNA-1273'	System	24 Feb 2021 16:10:26
DataPoint set to visible.	System	02 Feb 2021 15:59:54

US3492228

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:10:26

US3492228

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered '10:05'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:10:26

US3492228

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User entered '24 Feb 2021 10:05'	System	24 Feb 2021 16:10:26

US3492228

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:10:26

US3492228

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User entered 'ONCE'	System	24 Feb 2021 16:10:26

US3492228

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User entered 'INTRAMUSCULAR'	System	24 Feb 2021 16:10:26

US3492228

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	24 Feb 2021 15:21:18

US3492228

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User entered '1'	System	24 Feb 2021 15:21:18

US3492228

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:18:20

US3492228

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered '03 Mar 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:18:20

US3492228

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:18:20

US3492228

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:18:20

US3492228

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:18:33

US3492228

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:00
User entered '1'	System	03 Mar 2021 16:18:33

US3492228

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:31:50
	(b) (4)	
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	01 Apr 2021 16:49:02
	(b) (4)	

US3492228

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:31:50
	(b) (4)	
User entered '1 Apr 2021'	Gizelle Alvarez (b) (4)	01 Apr 2021 16:49:02
	(b) (4)	

US3492228

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:31:50
	(b) (4)	
User entered 'Clinic (Clinic)'	Gizelle Alvarez (b) (4)	01 Apr 2021 16:49:02
	(b) (4)	

US3492228

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:02

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	01 Apr 2021 16:49:02

US3492228

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:31:50
	(b) (4)	
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	01 Apr 2021 16:49:46
	(b) (4)	

US3492228

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:31:50
	(b) (4)	
User entered '1 Apr 2021'	Gizelle Alvarez (b) (4)	01 Apr 2021 16:49:46
	(b) (4)	

US3492228

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:31:50
	(b) (4)	
User entered '11:11'	Gizelle Alvarez (b) (4)	01 Apr 2021 16:49:46
	(b) (4)	

US3492228

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
User entered '1 Apr 2021 11:11'	System	01 Apr 2021 16:49:46

US3492228

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:31:50
	(b) (4)	
User entered '97.6' F	Gizelle Alvarez (b) (4)	01 Apr 2021 16:49:46
	(b) (4)	

US3492228

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:31:50
	(b) (4)	
User entered 'Other (Other)'	Gizelle Alvarez (b) (4)	01 Apr 2021 16:49:46
	(b) (4)	

US3492228

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:31:50
	(b) (4)	
User entered 'tympanic'	Gizelle Alvarez (b) (4)	01 Apr 2021 16:49:46
	(b) (4)	

US3492228

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:31:50
	(b) (4)	
User entered '59'	Gizelle Alvarez (b) (4)	01 Apr 2021 16:49:46
	(b) (4)	

US3492228

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Apr 2021 16:49:46

US3492228

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:31:50
	(b) (4)	
User entered '18'	Gizelle Alvarez (b) (4)	01 Apr 2021 16:49:46
	(b) (4)	

US3492228

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Apr 2021 16:49:46

US3492228

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:31:50
	(b) (4)	
User entered '121'	Gizelle Alvarez (b) (4)	01 Apr 2021 16:49:46
	(b) (4)	

US3492228

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 16:49:46

US3492228

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:31:50
	(b) (4)	
User entered '74'	Gizelle Alvarez (b) (4)	01 Apr 2021 16:49:46
	(b) (4)	

US3492228

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 16:49:46

US3492228

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:31:50
	(b) (4)	
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	01 Apr 2021 16:50:07
	(b) (4)	

US3492228

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:02

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:31:50
	(b) (4)	
User entered '1 Apr 2021'	Gizelle Alvarez (b) (4)	01 Apr 2021 16:50:07
	(b) (4)	

US3492228

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:31:50
	(b) (4)	
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	01 Apr 2021 16:49:59
	(b) (4)	

US3492228

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:31:50
	(b) (4)	
User entered '1 Apr 2021'	Gizelle Alvarez (b) (4)	01 Apr 2021 16:49:59
	(b) (4)	

US3492228

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:31:50
	(b) (4)	
User entered '11:30'	Gizelle Alvarez (b) (4)	01 Apr 2021 16:49:59
	(b) (4)	

US3492228

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
User entered '1 Apr 2021 11:30'	System	01 Apr 2021 16:49:59

US3492228

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:53:02

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	(b) (4) Nia Moragne-O'Neal (b) (4)	16 Dec 2020 17:53:41

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:22
User entered 'USA-US101-2020-mRNA-1273-P301000011'	System	16 Dec 2020 19:19:13
User entered 'New'	(b) (4), (b) (6)	16 Dec 2020 19:19:13

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User coded data point as SOC: Reproductive system and breast disorders, HLG: Vulvovaginal disorders (excl infections and inflammations), HLT: Vulvovaginal disorders NEC, PT: Vaginal haemorrhage, LLT: Vaginal bleeding - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Dec 2020 17:57:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Dec 2020 17:57:04
Data point term sent to Coder	System	16 Dec 2020 17:56:28
User entered 'Abnormal vaginal bleeding'	Nia Moragne-O'Neal (b) (4)	16 Dec 2020 17:56:00

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
	(b) (4)	
User entered 'No (N)'	Nia Moragne-O'Neal	16 Dec 2020 17:56:00
	(b) (4)	

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
	(b) (4)	
User entered 'No (N)'	Nia Moragne-O'Neal	16 Dec 2020 17:56:00
	(b) (4)	

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
	(b) (4)	
User entered 'No (N)'	Nia Moragne-O'Neal	16 Dec 2020 17:56:00
	(b) (4)	

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
	(b) (4)	
User entered '22 Nov 2020'	Nia Moragne-O'Neal	16 Dec 2020 17:56:00
	(b) (4)	

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
	(b) (4)	
User entered empty.	Nia Moragne-O'Neal	16 Dec 2020 17:56:00
	(b) (4)	

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Dec 2020 17:56:00

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Ian Feather (b) (4)	22 Jan 2021 18:38:54
	(b) (4)	
User entered 'Yes (Y)'	Nia Moragne-O'Neal	16 Dec 2020 17:56:00
	(b) (4)	

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
	(b) (4)	
User entered '15 Dec 2020' reason for change: New Information	Ian Feather (b) (4)	22 Jan 2021 18:38:54
	(b) (4)	
User entered empty.	Nia Moragne-O'Neal	16 Dec 2020 17:56:00
	(b) (4)	

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
	(b) (4)	
User entered empty.	Nia Moragne-O'Neal	16 Dec 2020 17:56:00
	(b) (4)	

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Dec 2020 17:56:00

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Nia Moragne-O'Neal (b) (4)	16 Dec 2020 17:56:00

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	17 Dec 2020 17:40:32
User entered 'No (N)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	17 Dec 2020 17:40:32
Query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' canceled (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 16:49:50
User opened query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 20:29:08
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	16 Dec 2020 17:56:00
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	16 Dec 2020 17:56:00

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
	(b) (4)	
User entered '0'	Nia Moragne-O'Neal	16 Dec 2020 17:56:00
	(b) (4)	

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
	(b) (4)	
User entered '0'	Nia Moragne-O'Neal	16 Dec 2020 17:56:00
	(b) (4)	

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
	(b) (4)	
User entered '0'	Nia Moragne-O'Neal	16 Dec 2020 17:56:00
	(b) (4)	

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
	(b) (4)	
User entered empty.	Nia Moragne-O'Neal	16 Dec 2020 17:56:00
	(b) (4)	

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
	(b) (4)	
User entered empty.	Nia Moragne-O'Neal	16 Dec 2020 17:56:00
	(b) (4)	

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
	(b) (4)	
User entered empty.	Nia Moragne-O'Neal	16 Dec 2020 17:56:00
	(b) (4)	

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
	(b) (4)	
User entered empty.	Nia Moragne-O'Neal	16 Dec 2020 17:56:00
	(b) (4)	

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
	(b) (4)	
User entered '0'	Nia Moragne-O'Neal	16 Dec 2020 17:56:00
	(b) (4)	

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
	(b) (4)	
User entered '0'	Nia Moragne-O'Neal	16 Dec 2020 17:56:00
	(b) (4)	

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
	(b) (4)	
User entered '0'	Nia Moragne-O'Neal	16 Dec 2020 17:56:00
	(b) (4)	

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Not Related (NOT RELATED)'	(b) (4) Nia Moragne-O'Neal (b) (4)	16 Dec 2020 17:56:00

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Not Related (NOT RELATED)'	(b) (4) Nia Moragne-O'Neal (b) (4)	16 Dec 2020 17:56:00

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4) Andrea Wendrow (b) (4)	17 Dec 2020 17:41:16
User entered 'None (NONE)'	Nia Moragne-O'Neal (b) (4)	16 Dec 2020 17:56:00

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	17 Dec 2020 17:41:16
User entered '1' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	17 Dec 2020 17:41:16
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	16 Dec 2020 17:56:00
User entered '0'	Nia Moragne-O'Neal (b) (4)	16 Dec 2020 17:56:00

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
	(b) (4)	
User entered '0'	Nia Moragne-O'Neal	16 Dec 2020 17:56:00
	(b) (4)	

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
	(b) (4)	
User entered '0'	Nia Moragne-O'Neal	16 Dec 2020 17:56:00
	(b) (4)	

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Ian Feather (b) (4)	22 Jan 2021 18:38:54
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Nia Moragne-O'Neal	16 Dec 2020 17:56:00
	(b) (4)	

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
	(b) (4)	
User entered empty.	Nia Moragne-O'Neal	16 Dec 2020 17:56:00
	(b) (4)	

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'participant reported abnormal vaginal bleeding that occurred 22nov2020, 12dec2020, 15dec2020. She reported that the blood seems old and is brown in color, and that it hurts during sex.'	Nia Moragne-O'Neal (b) (4)	16 Dec 2020 17:56:00

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	17 Dec 2020 17:40:32
User entered '1'	System	16 Dec 2020 17:56:00

US3492228

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:02

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	16 Dec 2020 17:56:00

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:53:02

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:32:04

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	15 Nov 2020 06:07:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Nov 2020 06:07:38
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	13 Nov 2020 20:02:57 13 Nov 2020 20:02:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 15:34:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 15:34:43
Data point term sent to Coder User entered 'metformin'	System (b) (4), (b) (6)	22 Sep 2020 15:33:34 22 Sep 2020 15:32:46

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:32:46

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. '(Site from DM).	(b) (4), (b) (6)	17 Nov 2020 15:14:50
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'participant has insulin resistance due to polycystic ovary syndrome, which is treated by metformin' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 20:03:02
User entered 'Insulin Resistance, secondary to Polycystic ovary syndrome' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 20:02:55
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. '(Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:46:24
User entered 'PCOS'	(b) (4), (b) (6)	22 Sep 2020 15:32:46

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:51:22
Signature has been broken.	Diana Bahena (b) (4) (b) (4)	11 Mar 2021 17:28:05
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered '500'	(b) (4), (b) (6) (b) (4)	22 Sep 2020 15:32:46

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:32:46

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:32:46

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:32:46

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:32:46

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:32:46

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:32:46

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '01 Jan 2018'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:32:46

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:32:46

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:32:46

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:32:46

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:32:46

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 15:32:46

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 15:32:46

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 15:32:46

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
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)	29 Sep 2020 19:43:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 19:43:43
Data point term sent to Coder User entered 'Ibuprofen'	System Addis Mekonnen (b) (4)	29 Sep 2020 19:42:18 29 Sep 2020 19:41:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User closed query 'Per DM CLR: Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update indication if applicable. If a condition is added to the indication please ensure to update Prophylaxis field to NO and as well AE eCRF is updated to reflect this update. Otherwise, please clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 10:05:25
Query 'Per DM CLR: Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update indication if applicable. If a condition is added to the indication please ensure to update Prophylaxis field to NO and as well AE eCRF is updated to reflect this update. Otherwise, please clarify.' answered with '-----Thank you. Corrected -----' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 20:55:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 20:54:42
User opened query 'Per DM CLR: Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update indication if applicable. If a condition is added to the indication please ensure to update Prophylaxis field to NO and as well AE eCRF is updated to reflect this update. Otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 02:49:13
User entered 'Yes (Y)'	Addis Mekonnen (b) (4) (b) (4)	29 Sep 2020 19:41:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
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 is 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 did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 10:06:38
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is 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 did not meet the AE reporting criteria.' answered with '----- taken for a solicited symptom indicated in e-dairy by participant. Does not meet AE reporting criteria-----' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 20:57:29

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:02

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 is 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 did not meet the AE reporting criteria.' (Site from DM). User entered 'Headache'	(b) (4), (b) (6) [REDACTED]	14 Dec 2020 02:49:04
	Addis Mekonnen (b) (4) [REDACTED]	29 Sep 2020 19:41:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:16
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered '400'	Addis Mekonnen (b) (4) (b) (4)	29 Sep 2020 19:41:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:16
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered 'mg (mg)'	Addis Mekonnen (b) (4) (b) (4)	29 Sep 2020 19:41:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:16
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered empty.	Addis Mekonnen (b) (4) (b) (4)	29 Sep 2020 19:41:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:16
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered 'once (ONCE)'	Addis Mekonnen (b) (4) (b) (4)	29 Sep 2020 19:41:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:16
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered empty.	Addis Mekonnen (b) (4) (b) (4)	29 Sep 2020 19:41:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:16
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered 'Oral (ORAL)'	Addis Mekonnen (b) (4) (b) (4)	29 Sep 2020 19:41:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:16
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered empty.	Addis Mekonnen (b) (4) (b) (4)	29 Sep 2020 19:41:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '26 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:07:36
User entered '27 Sep 2020'	Addis Mekonnen (b) (4) (b) (4)	29 Sep 2020 19:41:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:16
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered '0'	Addis Mekonnen (b) (4) (b) (4)	29 Sep 2020 19:41:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:16
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered 'No (N)'	Addis Mekonnen (b) (4) (b) (4)	29 Sep 2020 19:41:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '26 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:07:36
User entered '27 Sep 2020'	Addis Mekonnen (b) (4) (b) (4)	29 Sep 2020 19:41:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:16
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	Addis Mekonnen (b) (4) (b) (4)	29 Sep 2020 19:41:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:16
User entered empty.	System	29 Sep 2020 19:41:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:16
User entered empty.	System	29 Sep 2020 19:41:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:16
User entered empty.	System	29 Sep 2020 19:41:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:53:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:20
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
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)	13 Nov 2020 20:12:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Nov 2020 20:12:49
Data point term sent to Coder	System	13 Nov 2020 20:12:17
User entered 'ibuprofen'	(b) (4), (b) (6)	13 Nov 2020 20:11:31

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:53:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:20
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:11:31

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:53:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:20
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
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 is 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 did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 10:08:15
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is 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 did not meet the AE reporting criteria.' answered with '-----taken for solicited symptom indicated by participant in e-diary. Does not meet AE reporting criteria.-----' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 20:58:42

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:53:02

[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 is 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 did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 02:50:32
User entered 'headache'	(b) (4), (b) (6)	13 Nov 2020 20:11:31

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:53:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:20
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '400'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:11:31

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:53:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:20
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:11:31

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:53:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:20
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:11:31

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:53:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:20
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:11:31

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:53:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:20
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:11:31

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:53:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:20
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:11:31

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:53:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:20
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:11:31

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:53:02

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:20
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:11:31

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:53:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:20
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:11:31

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:53:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:20
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:11:31

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:20
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:11:31

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:53:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:20
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:11:31

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:53:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:20
User entered '2'	System	13 Nov 2020 20:11:31

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:53:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:20
User entered '1'	System	13 Nov 2020 20:11:31

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:53:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:20
User entered '804 (804)'	System	13 Nov 2020 20:11:31

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:02

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:26
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening)' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 10:17:56
Query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening)' answered with 'does not meet exclusion criteria. Started 3 days after second IP dose' (Site from DM).	Michelle Agnoli (b) (4) (b) (4)	17 Dec 2020 21:05:02
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening)' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 18:56:46
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR SYSTEMIC USE, ATC: RETINOIDS FOR TREATMENT OF ACNE, PRODUCT: ISOTRETINOIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Nov 2020 17:36:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Nov 2020 17:36:46
Data point term sent to Coder User entered 'isotretinoin'	System Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 17:36:14 15 Nov 2020 17:35:45

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:26
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 17:35:45

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:26
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered 'Acne'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 17:35:45

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:26
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered '20'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 17:35:45

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:26
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered 'mg (mg)'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 17:35:45

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:26
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 17:35:45

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:26
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered 'every other day (QOD)'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 17:35:45

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:26
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 17:35:45

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:26
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered 'Oral (ORAL)'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 17:35:45

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:26
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 17:35:45

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:26
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered '01 Nov 2020'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 17:35:45

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:26
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 17:35:45

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:26
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
Signature has been broken.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:23:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 15:23:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	(b) (4) Andrea Wendrow (b) (4)	15 Nov 2020 17:35:45

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:26
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
Signature has been broken.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:23:17
User entered '1 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 15:23:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	15 Nov 2020 17:35:45

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:26
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 17:35:45

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:26
User entered '1'	System	15 Nov 2020 17:35:45

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:26
User entered '2'	System	15 Nov 2020 17:35:45

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:26
User entered '804 (804)'	System	15 Nov 2020 17:35:45

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:02

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:30
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: COPPER - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 02:40:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 02:40:14
Data point term sent to Coder	System	23 Nov 2020 15:58:04
User closed query 'CDM Coding: Please provide the medication name and update the term with the generic and/or trade name to enable coding. Thank you' (Site from System).	System	23 Nov 2020 15:57:23
Query 'CDM Coding: Please provide the medication name and update the term with the generic and/or trade name to enable coding. Thank you' answered with 'Type added' (Site from System).	Marla Schwarber (b) (4)	23 Nov 2020 15:57:23
User entered 'Copper NON HORMONAL INTRAUTERINE DEVICE' reason for change: Per Query Resolution	Marla Schwarber (b) (4)	23 Nov 2020 15:57:09
User opened query 'CDM Coding: Please provide the medication name and update the term with the generic and/or trade name to enable coding. Thank you' (Site from System).	Coder Import (b) (4)	23 Nov 2020 14:59:51
Data point term sent to Coder	System	15 Nov 2020 18:04:31
User entered 'non hormonal intrauterine device'	Andrea Wendrow (b) (4)	15 Nov 2020 18:04:10

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:30
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 18:04:10

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:30
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered 'pregnancy prophylaxis'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 18:04:10

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:30
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered '1'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 18:04:10

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:30
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered 'Other (OTHER)'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 18:04:10

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:30
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered 'intrauterine device, no dose unit as non-drug containing'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 18:04:10

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:31:50
User closed query 'Per DM CLR-RQ: Response noted. However, frequency does not match ongoing dates. Consider updating Frequency to Other and specify Once (in place for multiple years). Thanks. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:10:38
Query 'Per DM CLR-RQ: Response noted. However, frequency does not match ongoing dates. Consider updating Frequency to Other and specify Once (in place for multiple years). Thanks. ' answered with 'updated' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	06 Apr 2021 19:34:11
Signature has been broken.	Marla Schwarber (b) (4) (b) (4)	06 Apr 2021 19:34:01
User entered 'other (OTHER)' reason for change: Per Query Resolution	Marla Schwarber (b) (4) (b) (4)	06 Apr 2021 19:34:01
User opened query 'Per DM CLR-RQ: Response noted. However, frequency does not match ongoing dates. Consider updating Frequency to Other and specify Once (in place for multiple years). Thanks. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 02:24:32
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4), (b) (6)	25 Mar 2021 13:15:03
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered with 'TUD is implanted once and remains in place for multiple years' (Site from System).	Marla Schwarber (b) (4) (b) (4)	24 Mar 2021 20:57:42
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	18 Mar 2021 15:24:06
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered 'once (ONCE)'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 18:04:10

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:30
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:31:50
Signature has been broken.	(b) (4) Marla Schwarber (b) (4)	06 Apr 2021 19:34:01
User entered 'Once in place for multiple years' reason for change: Per Query Resolution	(b) (4) Marla Schwarber (b) (4)	06 Apr 2021 19:34:01
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	15 Nov 2020 18:04:10

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:30
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered 'Other (OTHER)'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 18:04:10

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:30
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered 'intrauterine'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 18:04:10

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:02

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:30
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered 'UN UNK 2017'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 18:04:10

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:30
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 18:04:10

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:30
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
Signature has been broken.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:24:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 15:24:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered 'Yes (Y)'	(b) (4) Andrea Wendrow (b) (4)	15 Nov 2020 18:04:10

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:30
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
Signature has been broken.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:24:06
User entered '4 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 15:24:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	15 Nov 2020 18:04:10

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:30
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:14:37
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 18:04:10

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:30
User entered empty.	System	15 Nov 2020 18:04:10

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:30
User entered empty.	System	15 Nov 2020 18:04:10

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:30
User entered empty.	System	15 Nov 2020 18:04:10

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	25 Mar 2021 05:47:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 05:47:48
Data point term sent to Coder	System	24 Mar 2021 20:58:35
Data point term sent to Coder	System	18 Mar 2021 20:08:38
User entered 'Prenatal vitamin'	(b) (4), (b) (6)	18 Mar 2021 20:07:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:31:50
User closed query 'Per DM CLR: Please review response as supplements/vitamins are considered as prophylaxis. Update as appropriate. (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:09:20
Query 'Per DM CLR: Please review response as supplements/vitamins are considered as prophylaxis. Update as appropriate. answered with 'updated' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	06 Apr 2021 19:35:07
Signature has been broken.	Marla Schwarber (b) (4) (b) (4)	06 Apr 2021 19:34:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	06 Apr 2021 19:34:45
User opened query 'Per DM CLR: Please review response as supplements/vitamins are considered as prophylaxis. Update as appropriate. (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 02:25:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:51:22
User entered 'No (N)'	(b) (4), (b) (6)	18 Mar 2021 20:07:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'Vitamin supplement'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:07:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:31:50
User closed query 'Per DM CLR: Please provide the number of dose in numeric format. Update entry as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:09:44
Query 'Per DM CLR: Please provide the number of dose in numeric format. Update entry as appropriate. ' answered with 'updated' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	06 Apr 2021 19:35:13
Signature has been broken.	Marla Schwarber (b) (4) (b) (4)	06 Apr 2021 19:34:56
User entered '1' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	06 Apr 2021 19:34:56
User opened query 'Per DM CLR: Please provide the number of dose in numeric format. Update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 02:25:07
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:51:22
User entered 'one'	(b) (4), (b) (6)	18 Mar 2021 20:07:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:07:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:07:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:07:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:07:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Mar 2021 20:58:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Mar 2021 20:58:19
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Marla Schwarber (b) (4)	24 Mar 2021 20:58:19
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Mar 2021 20:07:47
User entered empty.	(b) (4), (b) (6)	18 Mar 2021 20:07:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:07:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered '8 Mar 2021'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:07:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:07:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:07:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:02

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:07:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:07:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Mar 2021 20:07:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Mar 2021 20:07:47

US3492228

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Mar 2021 20:07:47

US3492228

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:53:02

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:51:22
User entered 'No (N)'	(b) (4) Lorna Sanchez McCann (b) (4)	02 Mar 2021 15:54:26

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'USA-US101-2020-MRNA-1273-P301000011'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'No (N)'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

Death

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'No (N)'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'No (N)'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'No (N)'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'No (N)'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'No (N)'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'No (N)'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'Richard'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'Novak'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered '808 S. Wood St'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'Chicago'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'IL'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered '60612'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 16:50:35
User entered 'US'	System	16 Dec 2020 19:20:07

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '2'	(b) (4)	17 Dec 2020 16:50:48
User entered '1'	System	16 Dec 2020 19:20:07

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'USA-US101-2020-MRNA-1273-P301000011'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'No (N)'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

Death

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'No (N)'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'No (N)'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'No (N)'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'No (N)'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'No (N)'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'No (N)'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'Richard'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'Novak'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered '808 S. Wood St'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'Chicago'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'IL'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered '60612'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 16:50:35
User entered 'US'	System	16 Dec 2020 19:20:07

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '2'	(b) (4)	17 Dec 2020 16:50:48
User entered '1'	System	16 Dec 2020 19:20:07

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:53:02

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '16/Dec/2020 14:20'	(b) (4) System	16 Dec 2020 19:20:07

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:53:02

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.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 16:50:35
User entered '1'	(b) (4), (b) (6)	16 Dec 2020 19:20:07

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'USA-US101-2020-MRNA-1273-P301000011'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'No (N)'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

Death

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'No (N)'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'No (N)'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'No (N)'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'No (N)'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'No (N)'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'No (N)'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'Richard'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'Novak'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered '808 S. Wood St'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'Chicago'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered 'IL'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:19:54
User entered '60612'	System	16 Dec 2020 19:19:13

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 16:50:35
User entered 'US'	System	16 Dec 2020 19:20:07

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '2'	(b) (4)	17 Dec 2020 16:50:48
User entered '1'	System	16 Dec 2020 19:20:07

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:53:02

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '17/Dec/2020 16:50'	(b) (4) System	17 Dec 2020 16:50:48

US3492228

Folder: SAE USA-US101-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:53:02

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.	Richard Novak (b) (4)	15 Feb 2021 04:14:37
User entered '1'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 16:50:48