

US3492281 (Prod: UIC Project WISH CRS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:03:36

All time stamps listed in this document are displayed in GMT

US3492281

Form: Participant Creation

Data signed: (b) (4) 15 Feb 2021 04:31:53

Generated On: 10 Jun 2021 08:03:36

[Participant ID](#)

US3492281

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

US3492281

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Date of Birth (MMM yyyy)	(b) (6) 1978
Age	42
Age Units	YEARS
Age (Derived)	42
Sex	Female <input type="radio"/> Male <input checked="" 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	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	True
If race is Other, specify	LATINO
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Date of Informed Consent (<i>dd MMM yyyy</i>)	01 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

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 04:32:16

Generated On: 10 Jun 2021 08:03:36

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Apr 2021 16:34:42

Generated On: 10 Jun 2021 08:03:36

Condition	MAJOR PECTORALIS SURGICAL REPAIR
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

US3492281

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Apr 2021 16:34:42

Generated On: 10 Jun 2021 08:03:36

Condition	LEFT ULNAR FRACTURE WITH SURGICAL REPAIR
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

US3492281

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Apr 2021 16:34:42

Generated On: 10 Jun 2021 08:03:36

Condition	RECURRENT BILATERAL STYES
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JUN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JUN 2020
Stop Year (derived)	2020

US3492281

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Apr 2021 16:34:42

Generated On: 10 Jun 2021 08:03:36

Condition	HAIR LOSS
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3492281

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Apr 2021 16:34:42

Generated On: 10 Jun 2021 08:03:36

Condition	MAJOR PECTORALIS TEAR
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

US3492281

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Apr 2021 16:34:42

Generated On: 10 Jun 2021 08:03:36

Condition	COSMETIC SKIN PROCEDURE TO BILATERAL CHEEKS WITH JUVEDERM
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	01 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	09:35 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 09:35
Height (<i>xxx.x</i>)	170 cm
Weight (<i>xxx.x</i>)	71.7 kg
BMI (<i>xxx.x</i>)	24.80969 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 OCT 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 04:32:16

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 04:32:16

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	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 04:32:16

Generated On: 10 Jun 2021 08:03:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

What was the date of randomization? (dd MMM yyyy) 01 OCT 2020

What was the participant's randomization number? 116122

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 04:32:16

Generated On: 10 Jun 2021 08:03:36

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 04:32:16

Generated On: 10 Jun 2021 08:03:36

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 (dd MMM yyyy)	01 OCT 2020
Time of assessment (00:00-23:59)	09:35 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 09:35
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 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 04:32:16

Generated On: 10 Jun 2021 08:03:36

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 (dd MMM yyyy)	1 OCT 2020
Time of assessment (00:00-23:59)	10:32 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 10:32
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 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 04:32:16

Generated On: 10 Jun 2021 08:03:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 OCT 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 1 OCT 2020

What was the treatment time? (00:00-23:59) 10:26 (24 HR)

Treatment Date and Time (derived) 1 OCT 2020 10:26

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 04:32:16

Generated On: 10 Jun 2021 08:03:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 OCT 2020
Collection time (00:00-23:59)	09:50 (24 HR)
Collection date and time (derived)	01 OCT 2020 09:50

US3492281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Collection date (dd MMM yyyy)			01 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:00	01 OCT 2020 10:00
Nasopharyngeal Swab 2	No		

US3492281

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 10:48

PC Open Date & Time

01 OCT 2020 10:46

PC Close Date & Time

01 OCT 2020 13:16

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

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 97.5 °F

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

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

PC Time Stamp	02 OCT 2020 05:35
PC Open Date & Time	01 OCT 2020 14:11
PC Close Date & Time	02 OCT 2020 11:59

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

02 OCT 2020 12:02

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 23:13

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °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

04 OCT 2020 12:35

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:36

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

98.3 °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

05 OCT 2020 14:33

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

06 OCT 2020 12:01

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:36

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 12:00

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 10:50

PC Open Date & Time

01 OCT 2020 10:46

PC Close Date & Time

01 OCT 2020 13:16

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

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

02 OCT 2020 05:36

PC Open Date & Time

01 OCT 2020 14:11

PC Close Date & Time

02 OCT 2020 11:59

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 12:02

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 23:13

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 12:35

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 14:33

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 12:01

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:36

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

07 OCT 2020 12:00

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

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 ☐

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 10:49
PC Open Date & Time	01 OCT 2020 10:46
PC Close Date & Time	01 OCT 2020 13:16

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

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 ☐

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 05:35
PC Open Date & Time	01 OCT 2020 14:11
PC Close Date & Time	02 OCT 2020 11:59

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:36

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 ☒

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:36

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 ☒

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US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:36

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 23:13
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:36

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 ☒

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:36

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 12:36
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:36

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 ☒

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:36

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 14:34
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:36

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 ☒

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:36

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 12:01
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:36

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 ☒

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EAB) (1725)

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US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:36

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 12:01
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3492281

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492281

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492281

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492281

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492281

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3492281

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492281

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

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)	29 OCT 2020
Time of assessment (00:00-23:59)	09:29 (24 HR)
Vital Signs Date and Time (derived)	29 OCT 2020 09:29
Temperature (xxx.x)	36 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	EAR
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

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)	29 OCT 2020
Time of assessment (00:00-23:59)	11:02 (24 HR)
Vital Signs Date and Time (derived)	29 OCT 2020 11:02
Temperature (xxx.x)	97 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	EAR
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3492281

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 OCT 2020

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

US3492281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

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) 29 OCT 2020

What was the treatment time? (00:00-23:59) 10:48 (24 HR)

Treatment Date and Time (derived) 29 OCT 2020 10:48

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

US3492281

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 OCT 2020
Collection time (00:00-23:59)	09:50 (24 HR)
Collection date and time (derived)	29 OCT 2020 09:50

US3492281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Collection date (dd MMM yyyy)			29 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:57	29 OCT 2020 09:57
Nasopharyngeal Swab 2	No		

US3492281

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 OCT 2020 11:08

PC Open Date & Time

29 OCT 2020 11:08

PC Close Date & Time

29 OCT 2020 13:38

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

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	30 OCT 2020 01:16
PC Open Date & Time	29 OCT 2020 14:33
PC Close Date & Time	30 OCT 2020 11:59

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

30 OCT 2020 23:59

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

01 NOV 2020 09:29

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

02 NOV 2020 02:51

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:36

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 NOV 2020 15:23

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

03 NOV 2020 12:01

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:36

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 NOV 2020 12:01

PC Open Date & Time

04 NOV 2020 12:00

PC Close Date & Time

05 NOV 2020 11:59

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 OCT 2020 11:08

PC Open Date & Time

29 OCT 2020 11:08

PC Close Date & Time

29 OCT 2020 13:38

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

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

30 OCT 2020 01:16

PC Open Date & Time

29 OCT 2020 14:33

PC Close Date & Time

30 OCT 2020 11:59

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 OCT 2020 23:59

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 NOV 2020 09:29

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 NOV 2020 02:52

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 NOV 2020 15:23

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 NOV 2020 12:01

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:36

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

04 NOV 2020 12:01

PC Open Date & Time

04 NOV 2020 12:00

PC Close Date & Time

05 NOV 2020 11:59

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

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 ☐

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

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

No ☒

Yes ☐

PC Time stamp	29 OCT 2020 11:09
PC Open Date & Time	29 OCT 2020 11:08
PC Close Date & Time	29 OCT 2020 13:38

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

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 ☐

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

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

No ☒

Yes ☐

PC Time stamp	30 OCT 2020 01:17
PC Open Date & Time	29 OCT 2020 14:33
PC Close Date & Time	30 OCT 2020 11:59

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:36

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 ☒

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:36

Yes <input type="checkbox"/>	
PC Time stamp	31 OCT 2020 00:00
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:36

Yes <input type="checkbox"/>	
PC Time stamp	01 NOV 2020 09:30
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:36

Yes <input type="checkbox"/>	
PC Time stamp	02 NOV 2020 02:52
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:36

Yes <input type="checkbox"/>	
PC Time stamp	02 NOV 2020 15:23
PC Open Date & Time	02 NOV 2020 12:00
PC Close Date & Time	03 NOV 2020 11:59

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:36

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 ☒

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:36

Yes <input type="checkbox"/>	
PC Time stamp	03 NOV 2020 12:02
PC Open Date & Time	03 NOV 2020 12:00
PC Close Date & Time	04 NOV 2020 11:59

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:36

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 ☒

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:36

Yes <input type="checkbox"/>	
PC Time stamp	04 NOV 2020 12:01
PC Open Date & Time	04 NOV 2020 12:00
PC Close Date & Time	05 NOV 2020 11:59

US3492281

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492281

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3492281

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492281

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3492281

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492281

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:32:17

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 04:32:17

Generated On: 10 Jun 2021 08:03:36

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 NOV 2020
Time of assessment (00:00-23:59)	09:05 (24 HR)
Vital Signs Date and Time (derived)	25 NOV 2020 09:05
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)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492281

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:32:17

Generated On: 10 Jun 2021 08:03:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 NOV 2020

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

US3492281

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:32:17

Generated On: 10 Jun 2021 08:03:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 NOV 2020
Collection time (00:00-23:59)	09:12 (24 HR)
Collection date and time (derived)	25 NOV 2020 09:12

US3492281

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:32:17

Generated On: 10 Jun 2021 08:03:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 14:50:16
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 06:27:39
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

13 DEC 2020 10:05:18

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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	19 DEC 2020 05:21:30
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 DEC 2020 12:01:00
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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	02 JAN 2021 00:01:56
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

09 JAN 2021 13:15:34

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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	17 JAN 2021 22:42:45
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 00:02:59

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 JAN 2021 18:52:32
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

06 FEB 2021 00:02:09

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

16 FEB 2021 17:59:23

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 17:07:11

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

27 FEB 2021 00:45:50

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

06 MAR 2021 12:57:14

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

13 MAR 2021 05:09:44

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 10:09:07

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 08:58:42

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 21:44:18

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 APR 2021 15:59:31
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 00:10:07

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 APR 2021 11:47:37

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 01:52:52

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
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Patient Cloud Open Date & Time	15 MAY 2021 00:01
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Patient Cloud Close Date & Time	19 MAY 2021 23:59
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US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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 ☐

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2021 00:01
Patient Cloud Close Date & Time	21 JUL 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 AUG 2021 00:01
Patient Cloud Close Date & Time	25 AUG 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

Patient Cloud Open Date & Time	02 OCT 2021 00:01
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Patient Cloud Close Date & Time	06 OCT 2021 23:59
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US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 OCT 2021 00:01
Patient Cloud Close Date & Time	27 OCT 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 NOV 2021 00:01
Patient Cloud Close Date & Time	17 NOV 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 DEC 2021 00:01
Patient Cloud Close Date & Time	08 DEC 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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 ☐

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUN 2022 00:01
Patient Cloud Close Date & Time	15 JUN 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 JUN 2022 00:01
Patient Cloud Close Date & Time	29 JUN 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 JUL 2022 00:01
Patient Cloud Close Date & Time	13 JUL 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 JUL 2022 00:01
Patient Cloud Close Date & Time	27 JUL 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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 ☐

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

Patient Cloud Open Date & Time	13 AUG 2022 00:01
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Patient Cloud Close Date & Time	17 AUG 2022 23:59
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US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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 ☐

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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 ☐

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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 ☐

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2022 00:01
Patient Cloud Close Date & Time	26 OCT 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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 ☐

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

Patient Cloud Open Date & Time	12 NOV 2022 00:01
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Patient Cloud Close Date & Time	16 NOV 2022 23:59
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US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

19 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

26 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2022 23:59

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

[Patient Cloud Open Date & Time](#)

03 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2022 23:59

US3492281

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:03:36

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	No	01 MAR 2021 14:30:03

US3492281

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492281

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492281

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492281

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492281

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:56:30

Generated On: 10 Jun 2021 08:03:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492281

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:56:30

Generated On: 10 Jun 2021 08:03:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492281

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:56:30

Generated On: 10 Jun 2021 08:03:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492281

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:56:30

Generated On: 10 Jun 2021 08:03:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492281

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 30 Apr 2021 21:45:44

Generated On: 10 Jun 2021 08:03:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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	VISIT4

US3492281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Apr 2021 21:45:44

Generated On: 10 Jun 2021 08:03:36

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 APR 2021
Time of assessment (00:00-23:59)	11:42 (24 HR)
Vital Signs Date and Time (derived)	27 APR 2021 11:42
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)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492281

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Apr 2021 21:45:44

Generated On: 10 Jun 2021 08:03:36

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.

US3492281

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Apr 2021 21:45:44

Generated On: 10 Jun 2021 08:03:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 APR 2021
Collection time (00:00-23:59)	11:37 (24 HR)
Collection date and time (derived)	27 APR 2021 11:37

US3492281

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 30 Apr 2021 21:45:44

Generated On: 10 Jun 2021 08:03:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492281

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3492281

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:03:36

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"/>

US3492281

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:03:36

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3492281

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

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

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

Visit date (dd MMM yyyy)	15 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3492281

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

Form: Unblinding

Data signed: (b) (4) 26 Mar 2021 01:56:30

Generated On: 10 Jun 2021 08:03:36

Date of updated informed consent (<i>dd MMM yyyy</i>)	15 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>)	15 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

US3492281

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

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

US3492281

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

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)	15 JAN 2021
Time of assessment (00:00-23:59)	13:08 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 13:08
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3492281

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

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)	15 JAN 2021
Time of assessment (00:00-23:59)	14:00 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 14:00
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3492281

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

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 JAN 2021

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

US3492281

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

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

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) 15 JAN 2021

What was the treatment time? (00:00-23:59) 13:42 (24 HR)

Treatment Date and Time (derived) 15 JAN 2021 13:42

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

US3492281

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 JAN 2021
Collection time (00:00-23:59)	13:25 (24 HR)
Collection date and time (derived)	15 JAN 2021 13:25

US3492281

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 15 Feb 2021 04:31:54

Generated On: 10 Jun 2021 08:03:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 JAN 2021
Collection time (00:00 - 23:59)	13:32
Collection Date and Time (derived)	15 JAN 2021 13:32

US3492281

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

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:31:54

Generated On: 10 Jun 2021 08:03:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492281

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:32:16

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:31:54

Generated On: 10 Jun 2021 08:03:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 04:31:54

Generated On: 10 Jun 2021 08:03:36

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)	9 FEB 2021
Time of assessment (00:00-23:59)	09:05 (24 HR)
Vital Signs Date and Time (derived)	9 FEB 2021 09:05
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 04:31:54

Generated On: 10 Jun 2021 08:03:36

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)	9 FEB 2021
Time of assessment (00:00-23:59)	09:48 (24 HR)
Vital Signs Date and Time (derived)	9 FEB 2021 09:48
Temperature (xxx.x)	35.9 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3492281

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:31:54

Generated On: 10 Jun 2021 08:03:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 FEB 2021

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

US3492281

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 04:31:54

Generated On: 10 Jun 2021 08:03:36

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) 9 FEB 2021

What was the treatment time? (00:00-23:59) 09:45 (24 HR)

Treatment Date and Time (derived) 9 FEB 2021 09:45

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: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:31:54

Generated On: 10 Jun 2021 08:03:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492281

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:56:30

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:56:30

Generated On: 10 Jun 2021 08:03:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492281

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 01:56:30

Generated On: 10 Jun 2021 08:03:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3492281

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 01:56:30

Generated On: 10 Jun 2021 08:03:36

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	9 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	09:02 (24 HR)
Vital Signs Date and Time (derived)	9 MAR 2021 09:02
Temperature (<i>xxx.x</i>)	98.2 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>)	99 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492281

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 01:56:30

Generated On: 10 Jun 2021 08:03:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 MAR 2021

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

US3492281

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 01:56:30

Generated On: 10 Jun 2021 08:03:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	9 MAR 2021
Collection time (<i>00:00-23:59</i>)	09:05 (24 HR)
Collection date and time (derived)	9 MAR 2021 09:05

US3492281

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Feb 2021 04:31:53

Generated On: 10 Jun 2021 08:03:36

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 16:34:42

Generated On: 10 Jun 2021 08:03:36

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

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 16:34:42

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 16:34:42

Generated On: 10 Jun 2021 08:03:36

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 16:34:42

Generated On: 10 Jun 2021 08:03:36

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 16:34:42

Generated On: 10 Jun 2021 08:03:36

AEID	USA-US101-2021-MRNA-1273-P30 1000007
Adverse event	TORN TENDON IN LEFT WRIST
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	21 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	21 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	22 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 16:34:42

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 16:34:42

Generated On: 10 Jun 2021 08:03:36

PPT STRUCK BY MOTOR
VEHICLE AND RECEIVING
PHYSICAL
THERAPY-RECOVERED/RESOLV
ED PER PV REQUEST.
19APR2021- PPT REPORTS NOT
COMPLETELY HEALED BUT
IMPROVING.

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 16:34:42

Generated On: 10 Jun 2021 08:03:36

AEID

Adverse event

NASAL CONGESTION

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)

11 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

15 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 16:34:42

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Feb 2021 04:31:54

Generated On: 10 Jun 2021 08:03:36

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

Yes ☒

No ☐

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

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Mar 2021 01:56:30

Generated On: 10 Jun 2021 08:03:36

Name of Medication FINASTERIDE

Prophylaxis Yes ☐
No ☒

Indication HAIR LOSS

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Mar 2021 01:56:30

Generated On: 10 Jun 2021 08:03:36

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Mar 2021 01:56:30

Generated On: 10 Jun 2021 08:03:36

Name of Medication TENOFOVIR DISOPROXIL
FUMARATE AND
EMTRICITABINE (TRUVADA)

Prophylaxis Yes ☒
No ☐

Indication PREP

Dose per administration 300/200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Mar 2021 01:56:30

Generated On: 10 Jun 2021 08:03:36

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2020
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Mar 2021 01:56:30

Generated On: 10 Jun 2021 08:03:36

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐
No ☒

Indication BILATERAL RECURRENT STYES

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Mar 2021 01:56:30

Generated On: 10 Jun 2021 08:03:36

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN JUN 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Mar 2021 01:56:30

Generated On: 10 Jun 2021 08:03:36

Name of Medication DICLOFENAC

Prophylaxis Yes ☐
No ☒

Indication TORN TENDON LEFT WRIST

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Mar 2021 01:56:30

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Mar 2021 01:56:30

Generated On: 10 Jun 2021 08:03:36

Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐
No ☒

Indication TORN TENDON LEFT WRIST

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Mar 2021 01:56:30

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Mar 2021 01:56:30

Generated On: 10 Jun 2021 08:03:36

Name of Medication SALOMPAS (MENTHOL 3%,
METHYL SALICYLATE 10%)

Prophylaxis Yes ☐
No ☒

Indication TORN TENDON LEFT WRIST

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Mar 2021 01:56:30

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Mar 2021 01:56:30

Generated On: 10 Jun 2021 08:03:36

Name of Medication LIDOCANE 4% CREAM

Prophylaxis Yes ☐
No ☒

Indication TORN TENDON LEFT WRIST

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Mar 2021 01:56:30

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Mar 2021 01:56:30

Generated On: 10 Jun 2021 08:03:36

Name of Medication NEPROXIN

Prophylaxis Yes ☐
No ☒

Indication TORN TENDON LEFT WRIST

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Mar 2021 01:56:30

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 15 Feb 2021 04:31:54

Generated On: 10 Jun 2021 08:03:36

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3492281

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Mar 2021 01:56:30

Generated On: 10 Jun 2021 08:03:36

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
04 JAN 2021	PHYSICAL THERAPY FOR TORN TENDON IN LEFT WRIST	Adverse Event	

US3492281

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:03:36

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

US3492281

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:03:36

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 ☐

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 16:34:42

Generated On: 10 Jun 2021 08:03:36

SAEID	USA-US101-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	7

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 16:34:42

Generated On: 10 Jun 2021 08:03:36

SAEID	USA-US101-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	7
Date of submission (Pre-filled from custom function)	10/FEB/2021 09:19
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

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 16:34:42

Generated On: 10 Jun 2021 08:03:36

SAEID	USA-US101-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	7
Date of submission (Pre-filled from custom function)	18/FEB/2021 11:39
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

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 16:34:42

Generated On: 10 Jun 2021 08:03:36

SAEID	USA-US101-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	7
Date of submission (Pre-filled from custom function)	12/MAR/2021 13:41
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

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 16:34:42

Generated On: 10 Jun 2021 08:03:36

SAEID	USA-US101-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	7
Date of submission (Pre-filled from custom function)	22/MAR/2021 13:20
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Apr 2021 16:34:42

Generated On: 10 Jun 2021 08:03:36

SAEID	USA-US101-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	7
Date of submission (Pre-filled from custom function)	16/APR/2021 06:15
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

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form (6)

Data signed: (b) (4) 26 Apr 2021 16:34:42

Generated On: 10 Jun 2021 08:03:36

SAEID	USA-US101-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	7
Date of submission (Pre-filled from custom function)	20/APR/2021 09:32
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

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form (7)

Data signed: (b) (4) 26 Apr 2021 16:34:42

Generated On: 10 Jun 2021 08:03:36

SAEID	USA-US101-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	7
Date of submission (Pre-filled from custom function)	23/APR/2021 10:23
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

US3492281 (Prod: UIC Project WISH CRS)

US3492281

Form: Participant Creation

Generated On: 10 Jun 2021 08:03:36

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'US3492281'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 14:22:41

US3492281

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	Diana Bahena (b) (4)	01 Oct 2020 14:51:16

US3492281

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '01 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 14:22:43

US3492281

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Clinic (Clinic)'	Diana Bahena (b) (4)	01 Oct 2020 14:51:16

US3492281

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered 'SCRN'	System	01 Oct 2020 14:51:16

US3492281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:36

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered (b) (6) 1978'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 14:22:45

US3492281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:36

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '42'	Diana Bahena (b) (4)	01 Oct 2020 14:52:45

US3492281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:36

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered 'YEARS'	System	01 Oct 2020 14:52:45

US3492281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:36

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered '42'	System	01 Oct 2020 14:53:12

US3492281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:36

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Male (M)'	Diana Bahena (b) (4)	01 Oct 2020 14:52:45

US3492281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:36

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Diana Bahena (b) (4)	01 Oct 2020 14:52:45

US3492281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:36

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '0'	Diana Bahena (b) (4)	01 Oct 2020 14:52:45

US3492281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:36

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '0'	Diana Bahena (b) (4)	01 Oct 2020 14:52:45

US3492281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:36

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '0'	Diana Bahena (b) (4)	01 Oct 2020 14:52:45

US3492281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:36

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '0'	Diana Bahena (b) (4)	01 Oct 2020 14:52:45

US3492281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:36

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '0'	Diana Bahena (b) (4)	01 Oct 2020 14:52:45

US3492281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:36

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'I'	Diana Bahena (b) (4)	01 Oct 2020 14:52:45

US3492281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:36

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User closed query 'Race has been reported as Other, however If race is Other, specify is missing. Please provide.' (Site from System).	(b) (4)	
User entered 'latino' reason for change: Data Entry Error	System	01 Oct 2020 14:53:54
User opened query 'Race has been reported as Other, however If race is Other, specify is missing. Please provide.' (Site from System).	Diana Bahena (b) (4)	01 Oct 2020 14:53:54
User entered empty.	(b) (4)	
	System	01 Oct 2020 14:52:45
	Diana Bahena (b) (4)	01 Oct 2020 14:52:45
	(b) (4)	

US3492281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:36

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '0'	Diana Bahena (b) (4)	01 Oct 2020 14:52:45

US3492281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:36

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '0'	Diana Bahena (b) (4)	01 Oct 2020 14:52:45

US3492281

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:36

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User closed query 'Informed Consent Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	(b) (4)	
Query 'Informed Consent Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	01 Oct 2020 14:57:22
User opened query 'Informed Consent Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	01 Oct 2020 14:57:18
User entered '01 Oct 2020'	Diana Bahena (b) (4)	01 Oct 2020 14:53:12
	(b) (4)	

US3492281

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered 'Oct 2020'	System	01 Oct 2020 14:53:12

US3492281

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered '2020'	System	01 Oct 2020 14:53:12

US3492281

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:36

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Amendment 3 (3)'	Diana Bahena (b) (4)	01 Oct 2020 14:53:12

US3492281

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	Diana Bahena (b) (4)	01 Oct 2020 14:53:12

US3492281

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered empty.	Diana Bahena (b) (4)	01 Oct 2020 14:53:12

US3492281

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:36

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered empty.	Diana Bahena (b) (4)	01 Oct 2020 14:53:12

US3492281

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:36

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'No (N)'	Diana Bahena (b) (4)	01 Oct 2020 14:53:12

US3492281

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:36

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 14:22:43

US3492281

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:36

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered 'I'	System	01 Oct 2020 14:53:20

US3492281

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) Diana Bahena (b) (4)	01 Oct 2020 14:53:20

US3492281

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:03:36

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 21:37:58
User entered 'No (N)'	Diana Bahena (b) (4)	01 Oct 2020 14:54:06
	(b) (4)	

US3492281

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 11:59:59
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with '-----Thank you. New line added to MH.-----' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 19:47:10
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 06:30:20
User coded data point as SOC: Surgical and medical procedures, HLGT: Soft tissue therapeutic procedures, HLT: Muscle therapeutic procedures, PT: Muscle operation, LLT: Muscle operation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 23:27:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 23:27:03
Data point term sent to Coder	System	29 Oct 2020 21:38:58
User entered 'major pectoralis surgical repair'	Andrea Wendrow (b) (4) (b) (4)	29 Oct 2020 21:38:49

US3492281

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'UN UNK 2008'	Andrea Wendrow (b) (4)	29 Oct 2020 21:38:49

US3492281

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '0'	Andrea Wendrow (b) (4)	29 Oct 2020 21:38:49

US3492281

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'No (N)'	Andrea Wendrow (b) (4)	29 Oct 2020 21:38:49

US3492281

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'UN UNK 2008'	Andrea Wendrow (b) (4)	29 Oct 2020 21:38:49

US3492281

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '0'	Andrea Wendrow (b) (4)	29 Oct 2020 21:38:49

US3492281

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered 'Jan 2008'	System	29 Oct 2020 21:38:49

US3492281

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered '2008'	System	29 Oct 2020 21:38:49

US3492281

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered 'Jan 2008'	System	29 Oct 2020 21:38:49

US3492281

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered '2008'	System	29 Oct 2020 21:38:49

US3492281

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Fracture treatments (excl skull and spine), PT: Fracture treatment, LLT: Fracture repair - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 11:34:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 11:34:07
Data point term sent to Coder	System	29 Oct 2020 21:40:00
User entered 'Left ulnar fracture with surgical repair'	Andrea Wendrow (b) (4)	29 Oct 2020 21:39:39

US3492281

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'UN UNK 2017'	Andrea Wendrow (b) (4)	29 Oct 2020 21:39:39

US3492281

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '0'	Andrea Wendrow (b) (4)	29 Oct 2020 21:39:39

US3492281

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'No (N)'	Andrea Wendrow (b) (4)	29 Oct 2020 21:39:39

US3492281

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'UN UNK 2017'	Andrea Wendrow (b) (4)	29 Oct 2020 21:39:39

US3492281

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '0'	Andrea Wendrow (b) (4)	29 Oct 2020 21:39:39

US3492281

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered 'Jan 2017'	System	29 Oct 2020 21:39:39

US3492281

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered '2017'	System	29 Oct 2020 21:39:39

US3492281

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered 'Jan 2017'	System	29 Oct 2020 21:39:39

US3492281

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered '2017'	System	29 Oct 2020 21:39:39

US3492281

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Eye and eyelid infections, PT: Hordeolum, LLT: Style - version MedDRA\\23.0.	Coder Import (b) (4)	10 Dec 2020 22:15:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Dec 2020 22:15:59
Data point term sent to Coder	System	09 Dec 2020 23:42:29
User entered 'Recurrent bilateral styes'	Marla Schwarber (b) (4)	09 Dec 2020 23:41:53

US3492281

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'un UNK 2014'	Marla Schwarber (b) (4)	09 Dec 2020 23:41:53

US3492281

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '0'	Marla Schwarber (b) (4)	09 Dec 2020 23:41:53

US3492281

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'No (N)'	Marla Schwarber (b) (4)	09 Dec 2020 23:41:53

US3492281

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'un Jun 2020'	Marla Schwarber (b) (4)	09 Dec 2020 23:41:53

US3492281

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '0'	Marla Schwarber (b) (4)	09 Dec 2020 23:41:53

US3492281

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered 'Jan 2014'	System	09 Dec 2020 23:41:53

US3492281

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered '2014'	System	09 Dec 2020 23:41:53

US3492281

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered 'Jun 2020'	System	09 Dec 2020 23:41:53

US3492281

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered '2020'	System	09 Dec 2020 23:41:53

US3492281

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Alopecias, PT: Alopecia, LLT: Hair loss - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 23:44:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 23:44:42
Data point term sent to Coder	System	09 Dec 2020 23:43:30
User entered 'Hair loss'	Marla Schwarber (b) (4)	09 Dec 2020 23:42:35

US3492281

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'un UNK 2017'	Marla Schwarber (b) (4)	09 Dec 2020 23:42:35

US3492281

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '0'	Marla Schwarber (b) (4)	09 Dec 2020 23:42:35

US3492281

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	Marla Schwarber (b) (4)	09 Dec 2020 23:42:35

US3492281

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered empty.	Marla Schwarber (b) (4)	09 Dec 2020 23:42:35

US3492281

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '0'	Marla Schwarber (b) (4)	09 Dec 2020 23:42:35

US3492281

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered 'Jan 2017'	System	09 Dec 2020 23:42:35

US3492281

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered '2017'	System	09 Dec 2020 23:42:35

US3492281

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered empty.	System	09 Dec 2020 23:42:35

US3492281

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered empty.	System	09 Dec 2020 23:42:35

US3492281

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Muscle rupture, LLT: Torn muscle - version MedDRA\\23.0.	Coder Import (b) (4)	13 Jan 2021 14:16:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Jan 2021 14:16:00
Data point term sent to Coder	System	12 Jan 2021 19:46:18
User entered 'major pectoralis tear'	(b) (4), (b) (6)	12 Jan 2021 19:46:13

US3492281

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'UN UNK 2008'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:46:13

US3492281

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:46:13

US3492281

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:46:13

US3492281

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'UN UNK 2008'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:46:13

US3492281

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:46:13

US3492281

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered 'Jan 2008'	System	12 Jan 2021 19:46:13

US3492281

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered '2008'	System	12 Jan 2021 19:46:13

US3492281

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered 'Jan 2008'	System	12 Jan 2021 19:46:13

US3492281

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered '2008'	System	12 Jan 2021 19:46:13

US3492281

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Dermal filler injection, LLT: Dermal filler injection - version MedDRA\\23.0.	Coder Import (b) (4)	02 Apr 2021 08:12:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	02 Apr 2021 08:12:26
Data point term sent to Coder	System	01 Apr 2021 22:11:16
User entered 'Cosmetic skin Procedure to bilateral cheeks with Juvederm'	Andrea Wendrow (b) (4)	01 Apr 2021 22:10:29

US3492281

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:43
User entered 'un UNK 2018'	Andrea Wendrow (b) (4)	01 Apr 2021 22:10:29

US3492281

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:43
User entered '0'	Andrea Wendrow (b) (4)	01 Apr 2021 22:10:29

US3492281

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:43
User entered 'No (N)'	Andrea Wendrow (b) (4)	01 Apr 2021 22:10:29

US3492281

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:43
User entered 'un UNK 2018'	Andrea Wendrow (b) (4)	01 Apr 2021 22:10:29

US3492281

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:43
User entered '0'	Andrea Wendrow (b) (4)	01 Apr 2021 22:10:29

US3492281

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered 'Jan 2018'	System	01 Apr 2021 22:10:29

US3492281

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered '2018'	System	01 Apr 2021 22:10:29

US3492281

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered 'Jan 2018'	System	01 Apr 2021 22:10:29

US3492281

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered '2018'	System	01 Apr 2021 22:10:29

US3492281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	Diana Bahena (b) (4)	01 Oct 2020 14:55:09

US3492281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User closed query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	(b) (4)	01 Oct 2020 14:57:22
Query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	01 Oct 2020 14:57:22
User opened query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	01 Oct 2020 14:57:18
User entered '01 Oct 2020'	Diana Bahena (b) (4)	01 Oct 2020 14:55:09
	(b) (4)	

US3492281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '09:35'	Diana Bahena (b) (4)	01 Oct 2020 14:55:09

US3492281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered '01 Oct 2020 09:35'	System	01 Oct 2020 14:55:09

US3492281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '170' cm	(b) (4) Diana Bahena (b) (4)	01 Oct 2020 14:55:09
DataPoint set to visible.	(b) (4) System	01 Oct 2020 14:53:20

US3492281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '71.7' kg	(b) (4) Diana Bahena (b) (4)	01 Oct 2020 14:55:09
DataPoint set to visible.	(b) (4) System	01 Oct 2020 14:53:20

US3492281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered '24.80969'	System	01 Oct 2020 14:55:09
DataPoint set to visible.	System	01 Oct 2020 14:53:20

US3492281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered 'kg/m2'	System	01 Oct 2020 14:55:09
DataPoint set to visible.	System	01 Oct 2020 14:53:20

US3492281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered missing code ND - Not Done.	Diana Bahena (b) (4)	01 Oct 2020 14:55:09

US3492281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered empty.	Diana Bahena (b) (4)	01 Oct 2020 14:55:09

US3492281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered empty.	Diana Bahena (b) (4)	01 Oct 2020 14:55:09

US3492281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered missing code ND - Not Done.	Diana Bahena (b) (4)	01 Oct 2020 14:55:09

US3492281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered 'bpm'	System	01 Oct 2020 14:55:09

US3492281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered missing code ND - Not Done.	Diana Bahena (b) (4)	01 Oct 2020 14:55:09

US3492281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered 'breaths/min'	System	01 Oct 2020 14:55:09

US3492281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered missing code ND - Not Done.	(b) (4) Diana Bahena (b) (4)	01 Oct 2020 14:55:09

US3492281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered 'mmHg'	System	01 Oct 2020 14:55:09

US3492281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered missing code ND - Not Done.	Diana Bahena (b) (4)	01 Oct 2020 14:55:09

US3492281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User entered 'mmHg'	System	01 Oct 2020 14:55:09

US3492281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32

US3492281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32

US3492281

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) Diana Bahena (b) (4)	01 Oct 2020 14:55:29

US3492281

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User closed query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	(b) (4)	01 Oct 2020 14:57:22
Query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	01 Oct 2020 14:57:22
User opened query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	01 Oct 2020 14:57:18
User entered '01 Oct 2020'	Diana Bahena (b) (4)	01 Oct 2020 14:55:29
	(b) (4)	

US3492281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'No (N)'	Diana Bahena (b) (4)	01 Oct 2020 14:56:18

US3492281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'No (N)'	(b) (4) Diana Bahena (b) (4)	01 Oct 2020 14:56:18

US3492281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:36

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)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'No (N)'	(b) (4) Diana Bahena (b) (4) (b) (4)	01 Oct 2020 14:56:18

US3492281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:36

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)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'No (N)'	Diana Bahena (b) (4)	01 Oct 2020 14:56:18

US3492281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'No (N)'	Diana Bahena (b) (4)	01 Oct 2020 14:56:18

US3492281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:36

[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)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'No (N)'	Diana Bahena (b) (4)	01 Oct 2020 14:56:18

US3492281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:36

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)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'No (N)'	Diana Bahena (b) (4)	01 Oct 2020 14:56:18

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Folder: Screening

Form: Risk of Exposure

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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)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'No (N)'	Diana Bahena (b) (4)	01 Oct 2020 14:56:18

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:36

[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)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) Diana Bahena (b) (4)	01 Oct 2020 14:56:18

US3492281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:36

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)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'No (N)'	Diana Bahena (b) (4)	01 Oct 2020 14:56:18

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:36

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)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'No (N)'	Diana Bahena (b) (4)	01 Oct 2020 14:56:18

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:36

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 14:57:02
User entered 'No (N)' reason for change: Data Entry Error	Diana Bahena (b) (4)	01 Oct 2020 14:57:02
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	01 Oct 2020 14:56:18
	Diana Bahena (b) (4)	01 Oct 2020 14:56:18
	(b) (4)	

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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)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered empty.	Diana Bahena (b) (4)	01 Oct 2020 14:56:18

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '0'	Diana Bahena (b) (4)	01 Oct 2020 14:56:18

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:36

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '0'	Diana Bahena (b) (4)	01 Oct 2020 14:56:18

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:36

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)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '0'	Diana Bahena (b) (4)	01 Oct 2020 14:56:18

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:36

[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)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'I'	Diana Bahena (b) (4)	01 Oct 2020 14:56:18

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:36

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)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '0'	Diana Bahena (b) (4)	01 Oct 2020 14:56:18

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '0'	Diana Bahena (b) (4)	01 Oct 2020 14:56:18

US3492281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:36

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '0'	Diana Bahena (b) (4)	01 Oct 2020 14:56:18

US3492281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:36

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:06:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered empty.	Diana Bahena (b) (4)	01 Oct 2020 14:56:18

US3492281

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) Diana Bahena (b) (4)	01 Oct 2020 14:57:18

US3492281

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User closed query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	(b) (4)	
	System	01 Oct 2020 14:57:22
User entered '01 Oct 2020' reason for change: Data Entry Error	Diana Bahena (b) (4)	01 Oct 2020 14:57:22
	(b) (4)	
User opened query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	01 Oct 2020 14:57:18
User entered '01 Sep 2020'	Diana Bahena (b) (4)	01 Oct 2020 14:57:18
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Clinic (Clinic)'	Diana Bahena (b) (4)	01 Oct 2020 14:57:18

US3492281

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered 'VISIT1'	System	01 Oct 2020 14:57:18

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User closed query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	01 Oct 2020 14:57:22
Query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	01 Oct 2020 14:57:22
User opened query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	01 Oct 2020 14:57:18
User entered '01 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 14:48:24

US3492281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:36

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '116122'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 14:48:24

US3492281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 14:48:24

US3492281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'No (N)'	Diana Bahena (b) (4)	01 Oct 2020 14:57:36

US3492281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'No (N)'	Diana Bahena (b) (4)	01 Oct 2020 14:57:36

US3492281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'No (N)'	(b) (4) Diana Bahena (b) (4)	01 Oct 2020 14:57:36

US3492281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'No (N)'	(b) (4) Diana Bahena (b) (4)	01 Oct 2020 14:57:36

US3492281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:36

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'No (N)'	(b) (4) Diana Bahena (b) (4)	01 Oct 2020 14:57:36

US3492281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:36

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'No (N)'	(b) (4) Diana Bahena (b) (4)	01 Oct 2020 14:57:36
DataPoint set to visible.	(b) (4) System	01 Oct 2020 14:53:12

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered missing code ND - Not Done.	(b) (4) Diana Bahena (b) (4)	01 Oct 2020 14:59:05

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered missing code ND - Not Done.	(b) (4) Diana Bahena (b) (4)	01 Oct 2020 14:59:05

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered missing code ND - Not Done.	(b) (4) Diana Bahena (b) (4)	01 Oct 2020 14:59:05

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered missing code ND - Not Done.	(b) (4) Diana Bahena (b) (4)	01 Oct 2020 14:59:05

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User accepted default value 'Pre-Dose (PREDOSE)'	Diana Bahena (b) (4) (b) (4)	01 Oct 2020 14:59:05

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) Diana Bahena (b) (4)	01 Oct 2020 14:59:05

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '01 Oct 2020'	(b) (4) Diana Bahena (b) (4)	01 Oct 2020 14:59:05

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '09:35'	(b) (4) Diana Bahena (b) (4)	01 Oct 2020 14:59:05

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered '01 Oct 2020 09:35'	System	01 Oct 2020 14:59:05

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '36.5' C	Diana Bahena (b) (4)	01 Oct 2020 14:59:05

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Other (Other)'	Diana Bahena (b) (4)	01 Oct 2020 14:59:05

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'tympanic'	(b) (4) Diana Bahena (b) (4) (b) (4)	01 Oct 2020 14:59:05

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '76'	Diana Bahena (b) (4)	01 Oct 2020 14:59:05

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered 'bpm'	System	01 Oct 2020 14:59:05

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '20'	Diana Bahena (b) (4)	01 Oct 2020 14:59:05

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered 'breaths/min'	System	01 Oct 2020 14:59:05

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '132'	Diana Bahena (b) (4)	01 Oct 2020 14:59:05

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered 'mmHg'	System	01 Oct 2020 14:59:05

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '88'	(b) (4) Diana Bahena (b) (4)	01 Oct 2020 14:59:05

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered 'mmHg'	System	01 Oct 2020 14:59:05

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered missing code ND - Not Done.	(b) (4) Diana Bahena (b) (4)	01 Oct 2020 14:59:05

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered missing code ND - Not Done.	(b) (4) Diana Bahena (b) (4)	01 Oct 2020 14:59:05

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User accepted default value 'Post-Dose (POSTDOSE)'	Diana Bahena (b) (4) (b) (4)	01 Oct 2020 14:59:05

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 15:59:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Lorna Sanchez McCann	01 Oct 2020 15:59:48
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	01 Oct 2020 14:59:05
	Diana Bahena (b) (4)	01 Oct 2020 14:59:05
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '1 Oct 2020' reason for change: Data Entry Error	(b) (4)	01 Oct 2020 15:59:48
User entered empty.	Lorna Sanchez McCann (b) (4)	01 Oct 2020 14:59:05
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '10:32' reason for change: Data Entry Error	(b) (4)	01 Oct 2020 15:59:48
User entered empty.	Lorna Sanchez McCann (b) (4)	01 Oct 2020 14:59:05
	(b) (4)	

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered '1 Oct 2020 10:32'	System	01 Oct 2020 15:59:48
User entered empty.	System	01 Oct 2020 14:59:05

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '36.3' C reason for change: Data Entry Error	(b) (4)	01 Oct 2020 15:59:48
User entered empty.	Lorna Sanchez McCann (b) (4)	01 Oct 2020 14:59:05
	(b) (4)	

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	01 Oct 2020 15:59:48
User entered empty.	Lorna Sanchez McCann (b) (4)	01 Oct 2020 14:59:05
	(b) (4)	

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'tympanic' reason for change: Data Entry Error	(b) (4)	01 Oct 2020 15:59:48
User entered empty.	Lorna Sanchez McCann (b) (4)	01 Oct 2020 14:59:05
	(b) (4)	

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '72' reason for change: Data Entry Error	(b) (4)	01 Oct 2020 15:59:48
User entered empty.	Lorna Sanchez McCann (b) (4)	01 Oct 2020 14:59:05
	(b) (4)	

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered 'bpm'	System	01 Oct 2020 15:59:48
User entered empty.	System	01 Oct 2020 14:59:05

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '20' reason for change: Data Entry Error	(b) (4)	01 Oct 2020 15:59:48
User entered empty.	Lorna Sanchez McCann (b) (4)	01 Oct 2020 14:59:05
	(b) (4)	

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered 'breaths/min'	System	01 Oct 2020 15:59:48
User entered empty.	System	01 Oct 2020 14:59:05

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '123' reason for change: Data Entry Error	(b) (4)	01 Oct 2020 15:59:48
User entered empty.	Lorna Sanchez McCann (b) (4)	01 Oct 2020 14:59:05
	(b) (4)	

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered 'mmHg'	System	01 Oct 2020 15:59:48
User entered empty.	System	01 Oct 2020 14:59:05

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '73' reason for change: Data Entry Error	(b) (4)	01 Oct 2020 15:59:48
User entered empty.	Lorna Sanchez McCann (b) (4)	01 Oct 2020 14:59:05
	(b) (4)	

US3492281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered 'mmHg'	System	01 Oct 2020 15:59:48
User entered empty.	System	01 Oct 2020 14:59:05

US3492281

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) Diana Bahena (b) (4)	01 Oct 2020 14:59:40

US3492281

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '01 Oct 2020'	Diana Bahena (b) (4)	01 Oct 2020 14:59:40

US3492281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann	01 Oct 2020 15:33:07
	(b) (4)	

US3492281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered empty.	(b) (4) Lorna Sanchez McCann	01 Oct 2020 15:33:07
	(b) (4)	

US3492281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered empty.	Lorna Sanchez McCann (b) (4)	01 Oct 2020 15:33:07

US3492281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User entered 'MRNA-1273 OR PLACEBO'	System	01 Oct 2020 15:33:07

US3492281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '1 Oct 2020'	(b) (4) Lorna Sanchez McCann	01 Oct 2020 15:33:07
	(b) (4)	

US3492281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '10:26'	(b) (4) Lorna Sanchez McCann	01 Oct 2020 15:33:07
	(b) (4)	

US3492281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User entered '1 Oct 2020 10:26'	System	01 Oct 2020 15:33:07

US3492281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Left Arm (LEFT ARM)'	(b) (4) Lorna Sanchez McCann	01 Oct 2020 15:33:07
	(b) (4)	

US3492281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User entered 'ONCE'	System	01 Oct 2020 15:33:07

US3492281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User entered 'INTRAMUSCULAR'	System	01 Oct 2020 15:33:07

US3492281

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) Diana Bahena (b) (4)	01 Oct 2020 14:59:55

US3492281

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '01 Oct 2020'	(b) (4) Diana Bahena (b) (4)	01 Oct 2020 14:59:55
	(b) (4)	

US3492281

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '09:50'	Diana Bahena (b) (4)	01 Oct 2020 14:59:55

US3492281

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User entered '01 Oct 2020 09:50'	System	01 Oct 2020 14:59:55

US3492281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:03:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '01 Oct 2020'	(b) (4) Diana Bahena (b) (4)	01 Oct 2020 15:06:16
	(b) (4)	

US3492281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:03:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Diana Bahena (b) (4) (b) (4)	01 Oct 2020 15:06:16

US3492281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:03:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) Diana Bahena (b) (4)	01 Oct 2020 15:06:16
	(b) (4)	

US3492281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:03:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '10:00'	Diana Bahena (b) (4)	01 Oct 2020 15:06:16

US3492281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User entered '01 Oct 2020 10:00'	System	01 Oct 2020 15:06:16

US3492281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:03:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Diana Bahena (b) (4) (b) (4)	01 Oct 2020 15:06:16

US3492281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:03:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'No (N)'	(b) (4) Diana Bahena (b) (4)	01 Oct 2020 15:06:16
	(b) (4)	

US3492281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:03:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered empty.	Diana Bahena (b) (4)	01 Oct 2020 15:06:16

US3492281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User entered empty.	System	01 Oct 2020 15:06:16

US3492281

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) Diana Bahena (b) (4)	01 Oct 2020 15:00:19

US3492281

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User entered 'I'	System	01 Oct 2020 15:00:19

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	01 Oct 2020 15:33:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-01T10:48:03', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '41c0d589-add1-489a-ac6d-dbcc3f25169d' User entered 'Yes (Y)'	System	01 Oct 2020 15:48:27
	System	01 Oct 2020 15:48:27

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-01T10:48:09', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '41c0d589-add1-489a-ac6d-dbcc3f25169d' User entered '97.3'	System	01 Oct 2020 15:48:27
	System	01 Oct 2020 15:48:27

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-01T10:48:16', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '41c0d589-add1-489a-ac6d-dbcc3f25169d' User entered 'No (N)'	System	01 Oct 2020 15:48:27
	System	01 Oct 2020 15:48:27

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-01T10:48:22', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '41c0d589-add1-489a-ac6d-dbcc3f25169d' User entered '01 Oct 2020 10:48'	System	01 Oct 2020 15:48:27
	System	01 Oct 2020 15:48:27

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '01 Oct 2020 10:46'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '01 Oct 2020 13:16'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	01 Oct 2020 15:33:07
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T05:34:59', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '104b7892-0843-4cfe-869b-b4139c7b36d6' User entered 'Yes (Y)'	System	02 Oct 2020 10:35:24
	System	02 Oct 2020 10:35:24

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T05:35:07', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '104b7892-0843-4cfe-869b-b4139c7b36d6' User entered '97.5'	System	02 Oct 2020 10:35:24
	System	02 Oct 2020 10:35:24

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T05:35:13', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '104b7892-0843-4cfe-869b-b4139c7b36d6'	System	02 Oct 2020 10:35:24
User entered 'No (N)'	System	02 Oct 2020 10:35:24

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T05:35:18', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '104b7892-0843-4cfe-869b-b4139c7b36d6' User entered '02 Oct 2020 05:35'	System	02 Oct 2020 10:35:24
	System	02 Oct 2020 10:35:24

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '01 Oct 2020 14:11'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	01 Oct 2020 15:33:07
User entered 'Day 2'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T12:02:06', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '891b8aca-aef1-4d65-ac2b-5e5301aa8608' User entered 'Yes (Y)'	System	02 Oct 2020 17:02:55
	System	02 Oct 2020 17:02:55

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T12:02:15', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '891b8aca-aef1-4d65-ac2b-5e5301aa8608' User entered '98.3'	System	02 Oct 2020 17:02:55
	System	02 Oct 2020 17:02:55

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T12:02:18', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '891b8aca-aef1-4d65-ac2b-5e5301aa8608' User entered 'No (N)'	System	02 Oct 2020 17:02:55
	System	02 Oct 2020 17:02:55

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T12:02:21', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '891b8aca-aef1-4d65-ac2b-5e5301aa8608' User entered '02 Oct 2020 12:02'	System	02 Oct 2020 17:02:55
	System	02 Oct 2020 17:02:55

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	01 Oct 2020 15:33:07
User entered 'Day 3'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:36

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-03T23:12:57', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'd9d1c92e-8998-4032-baa4-122466654d3b' User entered 'Yes (Y)'	System	04 Oct 2020 04:13:14
	System	04 Oct 2020 04:13:14

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-03T23:13:04', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'd9d1c92e-8998-4032-baa4-122466654d3b' User entered '98.4'	System	04 Oct 2020 04:13:14
	System	04 Oct 2020 04:13:14

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-03T23:13:07', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'd9d1c92e-8998-4032-baa4-122466654d3b'	System	04 Oct 2020 04:13:14
User entered 'No (N)'	System	04 Oct 2020 04:13:14

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-03T23:13:12', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'd9d1c92e-8998-4032-baa4-122466654d3b' User entered '03 Oct 2020 23:13'	System	04 Oct 2020 04:13:14
	System	04 Oct 2020 04:13:14

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	01 Oct 2020 15:33:07
User entered 'Day 4'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:36

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-04T12:35:19', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '2fd91179-cf52-4f89-b989-5e76945dbb8b' User entered 'Yes (Y)'	System	04 Oct 2020 17:35:37
	System	04 Oct 2020 17:35:37

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-04T12:35:23', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '2fd91179-cf52-4f89-b989-5e76945dbb8b' User entered '96.3'	System	04 Oct 2020 17:35:37
	System	04 Oct 2020 17:35:37

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-04T12:35:26', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '2fd91179-cf52-4f89-b989-5e76945dbb8b' User entered 'No (N)'	System	04 Oct 2020 17:35:37
	System	04 Oct 2020 17:35:37

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-04T12:35:31', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '2fd91179-cf52-4f89-b989-5e76945dbb8b' User entered '04 Oct 2020 12:35'	System	04 Oct 2020 17:35:37
	System	04 Oct 2020 17:35:37

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	01 Oct 2020 15:33:07
User entered 'Day 5'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:36

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-05T14:33:13', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '34cade49-00aa-44b6-aa4e-4de0e81df47e' User entered 'Yes (Y)'	System	05 Oct 2020 19:33:32
	System	05 Oct 2020 19:33:32

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-05T14:33:21', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '34cade49-00aa-44b6-aa4e-4de0e81df47e' User entered '98.3'	System	05 Oct 2020 19:33:32
	System	05 Oct 2020 19:33:32

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-05T14:33:24', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '34cade49-00aa-44b6-aa4e-4de0e81df47e' User entered 'No (N)'	System	05 Oct 2020 19:33:32
	System	05 Oct 2020 19:33:32

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-05T14:33:28', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '34cade49-00aa-44b6-aa4e-4de0e81df47e' User entered '05 Oct 2020 14:33'	System	05 Oct 2020 19:33:32
	System	05 Oct 2020 19:33:32

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	01 Oct 2020 15:33:07
User entered 'Day 6'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-06T12:01:17', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '200ed580-e3cc-4a1d-ae73-d77602fa1c78' User entered 'Yes (Y)'	System	06 Oct 2020 17:01:55
	System	06 Oct 2020 17:01:55

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-06T12:01:22', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '200ed580-e3cc-4a1d-ae73-d77602fa1c78' User entered '97.6'	System	06 Oct 2020 17:01:55
	System	06 Oct 2020 17:01:55

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-06T12:01:25', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '200ed580-e3cc-4a1d-ae73-d77602fa1c78' User entered 'No (N)'	System	06 Oct 2020 17:01:55
	System	06 Oct 2020 17:01:55

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-06T12:01:27', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '200ed580-e3cc-4a1d-ae73-d77602fa1c78' User entered '06 Oct 2020 12:01'	System	06 Oct 2020 17:01:55
	System	06 Oct 2020 17:01:55

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	01 Oct 2020 15:33:07
User entered 'Day 7'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-07T12:00:25', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '2add7167-b5b2-42e7-a1b8-a4f4d9468acb' User entered 'Yes (Y)'	System	07 Oct 2020 17:00:49
	System	07 Oct 2020 17:00:49

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-07T12:00:30', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '2add7167-b5b2-42e7-a1b8-a4f4d9468acb' User entered '97.5'	System	07 Oct 2020 17:00:49
	System	07 Oct 2020 17:00:49

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-07T12:00:33', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '2add7167-b5b2-42e7-a1b8-a4f4d9468acb' User entered 'No (N)'	System	07 Oct 2020 17:00:49
	System	07 Oct 2020 17:00:49

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-07T12:00:36', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '2add7167-b5b2-42e7-a1b8-a4f4d9468acb' User entered '07 Oct 2020 12:00'	System	07 Oct 2020 17:00:49
	System	07 Oct 2020 17:00:49

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	01 Oct 2020 15:33:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-01T10:50:44', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'c917e5c5-b092-49c2-b53f-ec5d942e84c4' User entered 'None (1)'	System	01 Oct 2020 15:51:03
	System	01 Oct 2020 15:51:03

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-01T10:50:47', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'c917e5c5-b092-49c2-b53f-ec5d942e84c4' User entered 'No (N)'	System	01 Oct 2020 15:51:03
	System	01 Oct 2020 15:51:03

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-01T10:50:50', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'c917e5c5-b092-49c2-b53f-ec5d942e84c4' User entered 'No (N)'	System	01 Oct 2020 15:51:03
	System	01 Oct 2020 15:51:03

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-01T10:50:54', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'c917e5c5-b092-49c2-b53f-ec5d942e84c4' User entered 'None (1)'	System	01 Oct 2020 15:51:03
	System	01 Oct 2020 15:51:03

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-01T10:50:57', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'c917e5c5-b092-49c2-b53f-ec5d942e84c4' User entered '01 Oct 2020 10:50'	System	01 Oct 2020 15:51:03
	System	01 Oct 2020 15:51:03

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '01 Oct 2020 10:46'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '01 Oct 2020 13:16'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	01 Oct 2020 15:33:07
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T05:35:57', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '6e5f0982-b565-4831-8d41-757b8b51f226'	System	02 Oct 2020 10:36:15
User entered 'None (1)'	System	02 Oct 2020 10:36:15

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T05:35:59', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '6e5f0982-b565-4831-8d41-757b8b51f226' User entered 'No (N)'	System	02 Oct 2020 10:36:15
	System	02 Oct 2020 10:36:15

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T05:36:03', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '6e5f0982-b565-4831-8d41-757b8b51f226' User entered 'No (N)'	System	02 Oct 2020 10:36:15
	System	02 Oct 2020 10:36:15

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T05:36:05', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '6e5f0982-b565-4831-8d41-757b8b51f226'	System	02 Oct 2020 10:36:15
User entered 'None (1)'	System	02 Oct 2020 10:36:15

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T05:36:11', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '6e5f0982-b565-4831-8d41-757b8b51f226' User entered '02 Oct 2020 05:36'	System	02 Oct 2020 10:36:15
	System	02 Oct 2020 10:36:15

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '01 Oct 2020 14:11'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	01 Oct 2020 15:33:07
User entered 'Day 2'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T12:02:27', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'd1ae1727-1bea-4c46-95aa-292e027a562e' User entered 'None (1)'	System	02 Oct 2020 17:03:00
	System	02 Oct 2020 17:03:00

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T12:02:29', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'd1ae1727-1bea-4c46-95aa-292e027a562e' User entered 'No (N)'	System	02 Oct 2020 17:03:00
	System	02 Oct 2020 17:03:00

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T12:02:32', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'd1ae1727-1bea-4c46-95aa-292e027a562e' User entered 'No (N)'	System	02 Oct 2020 17:03:00
	System	02 Oct 2020 17:03:00

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T12:02:34', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'd1ae1727-1bea-4c46-95aa-292e027a562e' User entered 'None (1)'	System	02 Oct 2020 17:03:00
	System	02 Oct 2020 17:03:00

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T12:02:36', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'd1ae1727-1bea-4c46-95aa-292e027a562e' User entered '02 Oct 2020 12:02'	System	02 Oct 2020 17:03:00
	System	02 Oct 2020 17:03:00

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	01 Oct 2020 15:33:07
User entered 'Day 3'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-03T23:13:17', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'b1acc8cd-c8cb-42db-a787-bfb15d5c0716' User entered 'None (1)'	System	04 Oct 2020 04:13:30
	System	04 Oct 2020 04:13:30

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-03T23:13:19', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'b1acc8cd-c8cb-42db-a787-bfb15d5c0716' User entered 'No (N)'	System	04 Oct 2020 04:13:30
	System	04 Oct 2020 04:13:30

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-03T23:13:22', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'b1acc8cd-c8cb-42db-a787-bfb15d5c0716' User entered 'No (N)'	System	04 Oct 2020 04:13:30
	System	04 Oct 2020 04:13:30

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-03T23:13:24', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'b1acc8cd-c8cb-42db-a787-bfb15d5c0716' User entered 'None (1)'	System	04 Oct 2020 04:13:30
	System	04 Oct 2020 04:13:30

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-03T23:13:26', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'b1acc8cd-c8cb-42db-a787-bfb15d5c0716' User entered '03 Oct 2020 23:13'	System	04 Oct 2020 04:13:30
	System	04 Oct 2020 04:13:30

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	01 Oct 2020 15:33:07
User entered 'Day 4'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-04T12:35:34', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '7a608f86-4bf3-4301-828a-c4b332467bbc' User entered 'None (1)'	System	04 Oct 2020 17:36:02
	System	04 Oct 2020 17:36:02

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-04T12:35:36', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '7a608f86-4bf3-4301-828a-c4b332467bbc' User entered 'No (N)'	System	04 Oct 2020 17:36:02
	System	04 Oct 2020 17:36:02

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-04T12:35:53', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '7a608f86-4bf3-4301-828a-c4b332467bbc' User entered 'No (N)'	System	04 Oct 2020 17:36:02
	System	04 Oct 2020 17:36:02

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-04T12:35:56', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '7a608f86-4bf3-4301-828a-c4b332467bbc' User entered 'None (1)'	System	04 Oct 2020 17:36:02
	System	04 Oct 2020 17:36:02

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-04T12:35:59', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '7a608f86-4bf3-4301-828a-c4b332467bbc' User entered '04 Oct 2020 12:35'	System	04 Oct 2020 17:36:02
	System	04 Oct 2020 17:36:02

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	01 Oct 2020 15:33:07
User entered 'Day 5'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-05T14:33:32', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '7b1b739f-0683-4553-aef4-5984700b3730'	System	05 Oct 2020 19:33:44
User entered 'None (1)'	System	05 Oct 2020 19:33:44

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-05T14:33:34', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '7b1b739f-0683-4553-aef4-5984700b3730' User entered 'No (N)'	System	05 Oct 2020 19:33:44
	System	05 Oct 2020 19:33:44

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-05T14:33:36', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '7b1b739f-0683-4553-aef4-5984700b3730' User entered 'No (N)'	System	05 Oct 2020 19:33:44
	System	05 Oct 2020 19:33:44

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-05T14:33:38', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '7b1b739f-0683-4553-aef4-5984700b3730' User entered 'None (1)'	System	05 Oct 2020 19:33:44
	System	05 Oct 2020 19:33:44

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-05T14:33:41', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '7b1b739f-0683-4553-aef4-5984700b3730' User entered '05 Oct 2020 14:33'	System	05 Oct 2020 19:33:44
	System	05 Oct 2020 19:33:44

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	01 Oct 2020 15:33:07
User entered 'Day 6'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-06T12:01:30', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '53214231-bb4f-4616-8bca-cfe19d388d38' User entered 'None (1)'	System	06 Oct 2020 17:02:11
	System	06 Oct 2020 17:02:11

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-06T12:01:33', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '53214231-bb4f-4616-8bca-cfe19d388d38' User entered 'No (N)'	System	06 Oct 2020 17:02:11
	System	06 Oct 2020 17:02:11

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-06T12:01:36', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '53214231-bb4f-4616-8bca-cfe19d388d38' User entered 'No (N)'	System	06 Oct 2020 17:02:11
	System	06 Oct 2020 17:02:11

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-06T12:01:38', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '53214231-bb4f-4616-8bca-cfe19d388d38' User entered 'None (1)'	System	06 Oct 2020 17:02:11
	System	06 Oct 2020 17:02:11

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-06T12:01:40', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '53214231-bb4f-4616-8bca-cfe19d388d38' User entered '06 Oct 2020 12:01'	System	06 Oct 2020 17:02:11
	System	06 Oct 2020 17:02:11

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	01 Oct 2020 15:33:07
User entered 'Day 7'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-07T12:00:39', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'fb082941-f298-4642-ab80-befb808f48a1'	System	07 Oct 2020 17:01:10
User entered 'None (1)'	System	07 Oct 2020 17:01:10

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-07T12:00:40', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'fb082941-f298-4642-ab80-befb808f48a1' User entered 'No (N)'	System	07 Oct 2020 17:01:10
	System	07 Oct 2020 17:01:10

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-07T12:00:42', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'fb082941-f298-4642-ab80-befb808f48a1' User entered 'No (N)'	System	07 Oct 2020 17:01:10
	System	07 Oct 2020 17:01:10

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-07T12:00:44', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'fb082941-f298-4642-ab80-befb808f48a1'	System	07 Oct 2020 17:01:10
User entered 'None (1)'	System	07 Oct 2020 17:01:10

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-07T12:00:46', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'fb082941-f298-4642-ab80-befb808f48a1' User entered '07 Oct 2020 12:00'	System	07 Oct 2020 17:01:10
	System	07 Oct 2020 17:01:10

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	01 Oct 2020 15:33:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-01T10:48:39', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '24eeea68-202e-434c-8dc0-1131a7bb19eb' User entered 'None (0)'	System	01 Oct 2020 15:49:26
	System	01 Oct 2020 15:49:26

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-01T10:48:45', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '24eeea68-202e-434c-8dc0-1131a7bb19eb' User entered 'None (0)'	System	01 Oct 2020 15:49:26
	System	01 Oct 2020 15:49:26

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-01T10:48:49', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '24eeea68-202e-434c-8dc0-1131a7bb19eb' User entered 'None (0)'	System	01 Oct 2020 15:49:26
	System	01 Oct 2020 15:49:26

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-01T10:48:54', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '24eeea68-202e-434c-8dc0-1131a7bb19eb' User entered 'None (0)'	System	01 Oct 2020 15:49:26
	System	01 Oct 2020 15:49:26

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-01T10:48:57', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '24eeea68-202e-434c-8dc0-1131a7bb19eb' User entered 'None (0)'	System	01 Oct 2020 15:49:26
	System	01 Oct 2020 15:49:26

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-01T10:48:59', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '24eeea68-202e-434c-8dc0-1131a7bb19eb' User entered 'None (0)'	System	01 Oct 2020 15:49:26
	System	01 Oct 2020 15:49:26

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-01T10:49:04', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '24eeea68-202e-434c-8dc0-1131a7bb19eb' User entered 'No (N)'	System	01 Oct 2020 15:49:26
	System	01 Oct 2020 15:49:26

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-01T10:49:08', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '24eeea68-202e-434c-8dc0-1131a7bb19eb' User entered '01 Oct 2020 10:49'	System	01 Oct 2020 15:49:26
	System	01 Oct 2020 15:49:26

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '01 Oct 2020 10:46'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '01 Oct 2020 13:16'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	01 Oct 2020 15:33:07
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T05:35:32', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '4f59725e-11dd-4b56-8ec2-fc0f92f3b4eb' User entered 'None (0)'	System	02 Oct 2020 10:35:53
	System	02 Oct 2020 10:35:53

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T05:35:34', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '4f59725e-11dd-4b56-8ec2-fc0f92f3b4eb' User entered 'None (0)'	System	02 Oct 2020 10:35:53
	System	02 Oct 2020 10:35:53

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T05:35:37', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '4f59725e-11dd-4b56-8ec2-fc0f92f3b4eb' User entered 'None (0)'	System	02 Oct 2020 10:35:53
	System	02 Oct 2020 10:35:53

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T05:35:39', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '4f59725e-11dd-4b56-8ec2-fc0f92f3b4eb' User entered 'None (0)'	System	02 Oct 2020 10:35:53
	System	02 Oct 2020 10:35:53

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T05:35:41', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '4f59725e-11dd-4b56-8ec2-fc0f92f3b4eb' User entered 'None (0)'	System	02 Oct 2020 10:35:53
	System	02 Oct 2020 10:35:53

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T05:35:43', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '4f59725e-11dd-4b56-8ec2-fc0f92f3b4eb' User entered 'None (0)'	System	02 Oct 2020 10:35:53
	System	02 Oct 2020 10:35:53

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T05:35:46', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '4f59725e-11dd-4b56-8ec2-fc0f92f3b4eb' User entered 'No (N)'	System	02 Oct 2020 10:35:53
	System	02 Oct 2020 10:35:53

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T05:35:49', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '4f59725e-11dd-4b56-8ec2-fc0f92f3b4eb' User entered '02 Oct 2020 05:35'	System	02 Oct 2020 10:35:53
	System	02 Oct 2020 10:35:53

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '01 Oct 2020 14:11'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	01 Oct 2020 15:33:07
User entered 'Day 2'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T12:02:42', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '6ea4b46f-0a91-41e7-a4b6-bf7408b6d5b3' User entered 'None (0)'	System	02 Oct 2020 17:03:14
	System	02 Oct 2020 17:03:14

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T12:02:44', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '6ea4b46f-0a91-41e7-a4b6-bf7408b6d5b3' User entered 'None (0)'	System	02 Oct 2020 17:03:14
	System	02 Oct 2020 17:03:14

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T12:02:46', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '6ea4b46f-0a91-41e7-a4b6-bf7408b6d5b3' User entered 'None (0)'	System	02 Oct 2020 17:03:14
	System	02 Oct 2020 17:03:14

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T12:02:48', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '6ea4b46f-0a91-41e7-a4b6-bf7408b6d5b3' User entered 'None (0)'	System	02 Oct 2020 17:03:14
	System	02 Oct 2020 17:03:14

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T12:02:50', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '6ea4b46f-0a91-41e7-a4b6-bf7408b6d5b3' User entered 'None (0)'	System	02 Oct 2020 17:03:14
	System	02 Oct 2020 17:03:14

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T12:02:52', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '6ea4b46f-0a91-41e7-a4b6-bf7408b6d5b3' User entered 'None (0)'	System	02 Oct 2020 17:03:14
	System	02 Oct 2020 17:03:14

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T12:02:54', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '6ea4b46f-0a91-41e7-a4b6-bf7408b6d5b3' User entered 'No (N)'	System	02 Oct 2020 17:03:14
	System	02 Oct 2020 17:03:14

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-02T12:02:57', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '6ea4b46f-0a91-41e7-a4b6-bf7408b6d5b3' User entered '02 Oct 2020 12:02'	System	02 Oct 2020 17:03:14
	System	02 Oct 2020 17:03:14

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	01 Oct 2020 15:33:07
User entered 'Day 3'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-03T23:13:30', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'c743368c-666a-4691-8452-d97137e56d84' User entered 'None (0)'	System	04 Oct 2020 04:13:51
	System	04 Oct 2020 04:13:51

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-03T23:13:33', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'c743368c-666a-4691-8452-d97137e56d84' User entered 'None (0)'	System	04 Oct 2020 04:13:51
	System	04 Oct 2020 04:13:51

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-03T23:13:36', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'c743368c-666a-4691-8452-d97137e56d84' User entered 'None (0)'	System	04 Oct 2020 04:13:51
	System	04 Oct 2020 04:13:51

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-03T23:13:38', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'c743368c-666a-4691-8452-d97137e56d84' User entered 'None (0)'	System	04 Oct 2020 04:13:51
	System	04 Oct 2020 04:13:51

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-03T23:13:40', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'c743368c-666a-4691-8452-d97137e56d84' User entered 'None (0)'	System	04 Oct 2020 04:13:51
	System	04 Oct 2020 04:13:51

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-03T23:13:42', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'c743368c-666a-4691-8452-d97137e56d84' User entered 'None (0)'	System	04 Oct 2020 04:13:51
	System	04 Oct 2020 04:13:51

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-03T23:13:46', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'c743368c-666a-4691-8452-d97137e56d84'	System	04 Oct 2020 04:13:51
User entered 'No (N)'	System	04 Oct 2020 04:13:51

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-03T23:13:49', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'c743368c-666a-4691-8452-d97137e56d84' User entered '03 Oct 2020 23:13'	System	04 Oct 2020 04:13:51
	System	04 Oct 2020 04:13:51

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	01 Oct 2020 15:33:07
User entered 'Day 4'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-04T12:36:08', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'c46f25b0-cca2-42d9-a650-466cb0a1eda4' User entered 'None (0)'	System	04 Oct 2020 17:36:41
	System	04 Oct 2020 17:36:41

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-04T12:36:10', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'c46f25b0-cca2-42d9-a650-466cb0a1eda4' User entered 'None (0)'	System	04 Oct 2020 17:36:41
	System	04 Oct 2020 17:36:41

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-04T12:36:12', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'c46f25b0-cca2-42d9-a650-466cb0a1eda4' User entered 'None (0)'	System	04 Oct 2020 17:36:41
	System	04 Oct 2020 17:36:41

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-04T12:36:14', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'c46f25b0-cca2-42d9-a650-466cb0a1eda4' User entered 'None (0)'	System	04 Oct 2020 17:36:41
	System	04 Oct 2020 17:36:41

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-04T12:36:16', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'c46f25b0-cca2-42d9-a650-466cb0a1eda4' User entered 'None (0)'	System	04 Oct 2020 17:36:41
	System	04 Oct 2020 17:36:41

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-04T12:36:18', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'c46f25b0-cca2-42d9-a650-466cb0a1eda4' User entered 'None (0)'	System	04 Oct 2020 17:36:41
	System	04 Oct 2020 17:36:41

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-04T12:36:28', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'c46f25b0-cca2-42d9-a650-466cb0a1eda4' User entered 'No (N)'	System	04 Oct 2020 17:36:41
	System	04 Oct 2020 17:36:41

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-04T12:36:38', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'c46f25b0-cca2-42d9-a650-466cb0a1eda4' User entered '04 Oct 2020 12:36'	System	04 Oct 2020 17:36:41
	System	04 Oct 2020 17:36:41

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	01 Oct 2020 15:33:07
User entered 'Day 5'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-05T14:33:45', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '422f3da5-2347-476c-934d-f66d32c89776' User entered 'None (0)'	System	05 Oct 2020 19:34:04
	System	05 Oct 2020 19:34:04

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-05T14:33:47', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '422f3da5-2347-476c-934d-f66d32c89776' User entered 'None (0)'	System	05 Oct 2020 19:34:04
	System	05 Oct 2020 19:34:04

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-05T14:33:49', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '422f3da5-2347-476c-934d-f66d32c89776' User entered 'None (0)'	System	05 Oct 2020 19:34:04
	System	05 Oct 2020 19:34:04

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-05T14:33:51', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '422f3da5-2347-476c-934d-f66d32c89776' User entered 'None (0)'	System	05 Oct 2020 19:34:04
	System	05 Oct 2020 19:34:04

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-05T14:33:53', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '422f3da5-2347-476c-934d-f66d32c89776' User entered 'None (0)'	System	05 Oct 2020 19:34:04
	System	05 Oct 2020 19:34:04

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-05T14:33:55', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '422f3da5-2347-476c-934d-f66d32c89776' User entered 'None (0)'	System	05 Oct 2020 19:34:04
	System	05 Oct 2020 19:34:04

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-05T14:33:57', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '422f3da5-2347-476c-934d-f66d32c89776' User entered 'No (N)'	System	05 Oct 2020 19:34:04
	System	05 Oct 2020 19:34:04

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-05T14:34:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '422f3da5-2347-476c-934d-f66d32c89776' User entered '05 Oct 2020 14:34'	System	05 Oct 2020 19:34:04
	System	05 Oct 2020 19:34:04

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	01 Oct 2020 15:33:07
User entered 'Day 6'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-06T12:01:43', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'ee473fc0-9435-4a41-a25d-6e8454d5397b' User entered 'None (0)'	System	06 Oct 2020 17:02:25
	System	06 Oct 2020 17:02:25

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-06T12:01:46', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'ee473fc0-9435-4a41-a25d-6e8454d5397b' User entered 'None (0)'	System	06 Oct 2020 17:02:25
	System	06 Oct 2020 17:02:25

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-06T12:01:49', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'ee473fc0-9435-4a41-a25d-6e8454d5397b' User entered 'None (0)'	System	06 Oct 2020 17:02:25
	System	06 Oct 2020 17:02:25

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-06T12:01:51', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'ee473fc0-9435-4a41-a25d-6e8454d5397b' User entered 'None (0)'	System	06 Oct 2020 17:02:25
	System	06 Oct 2020 17:02:25

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-06T12:01:53', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'ee473fc0-9435-4a41-a25d-6e8454d5397b' User entered 'None (0)'	System	06 Oct 2020 17:02:25
	System	06 Oct 2020 17:02:25

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-06T12:01:54', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'ee473fc0-9435-4a41-a25d-6e8454d5397b' User entered 'None (0)'	System	06 Oct 2020 17:02:25
	System	06 Oct 2020 17:02:25

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-06T12:01:56', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'ee473fc0-9435-4a41-a25d-6e8454d5397b' User entered 'No (N)'	System	06 Oct 2020 17:02:25
	System	06 Oct 2020 17:02:25

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-06T12:01:58', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'ee473fc0-9435-4a41-a25d-6e8454d5397b' User entered '06 Oct 2020 12:01'	System	06 Oct 2020 17:02:25
	System	06 Oct 2020 17:02:25

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	01 Oct 2020 15:33:07
User entered 'Day 7'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-07T12:00:49', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'f754375d-8fd4-4162-9571-348b6c8ce00e' User entered 'None (0)'	System	07 Oct 2020 17:01:29
	System	07 Oct 2020 17:01:29

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-07T12:00:52', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'f754375d-8fd4-4162-9571-348b6c8ce00e' User entered 'None (0)'	System	07 Oct 2020 17:01:29
	System	07 Oct 2020 17:01:29

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-07T12:00:54', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'f754375d-8fd4-4162-9571-348b6c8ce00e' User entered 'None (0)'	System	07 Oct 2020 17:01:29
	System	07 Oct 2020 17:01:29

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-07T12:00:55', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'f754375d-8fd4-4162-9571-348b6c8ce00e' User entered 'None (0)'	System	07 Oct 2020 17:01:29
	System	07 Oct 2020 17:01:29

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-07T12:00:57', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'f754375d-8fd4-4162-9571-348b6c8ce00e' User entered 'None (0)'	System	07 Oct 2020 17:01:29
	System	07 Oct 2020 17:01:29

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-07T12:00:58', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'f754375d-8fd4-4162-9571-348b6c8ce00e' User entered 'None (0)'	System	07 Oct 2020 17:01:29
	System	07 Oct 2020 17:01:29

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-07T12:01:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'f754375d-8fd4-4162-9571-348b6c8ce00e' User entered 'No (N)'	System	07 Oct 2020 17:01:29
	System	07 Oct 2020 17:01:29

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-07T12:01:02', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'f754375d-8fd4-4162-9571-348b6c8ce00e' User entered '07 Oct 2020 12:01'	System	07 Oct 2020 17:01:29
	System	07 Oct 2020 17:01:29

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 15:33:07

US3492281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 15:33:07

US3492281

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:21:48

US3492281

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:21:48

US3492281

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:21:48

US3492281

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:21:48

US3492281

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:21:51

US3492281

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User entered 'I'	System	09 Oct 2020 16:21:51

US3492281

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	16 Oct 2020 15:58:53

US3492281

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '15 Oct 2020'	(b) (4) Lorna Sanchez McCann (b) (4)	16 Oct 2020 15:58:53

US3492281

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lorna Sanchez McCann (b) (4)	16 Oct 2020 15:58:53

US3492281

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered empty.	Lorna Sanchez McCann (b) (4)	16 Oct 2020 15:58:53

US3492281

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann	16 Oct 2020 15:58:58
	(b) (4)	

US3492281

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User entered 'I'	System	16 Oct 2020 15:58:58

US3492281

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) Diana Bahena (b) (4)	23 Oct 2020 14:56:11

US3492281

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '22 Oct 2020'	Diana Bahena (b) (4)	23 Oct 2020 14:56:11

US3492281

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Contact Made (CONTACT MADE)'	Diana Bahena (b) (4)	23 Oct 2020 14:56:11

US3492281

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered empty.	(b) (4) Diana Bahena (b) (4) (b) (4)	23 Oct 2020 14:56:11

US3492281

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	Diana Bahena (b) (4)	23 Oct 2020 14:56:19

US3492281

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User entered 'I'	System	23 Oct 2020 14:56:19

US3492281

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:17:00

US3492281

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:17:00

US3492281

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:17:00

US3492281

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered 'VISIT2'	System	29 Oct 2020 15:17:00

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User accepted default value 'Pre-Dose (PREDOSE)'	Andrea Wendrow (b) (4)	29 Oct 2020 21:47:27
	(b) (4)	

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '29 Oct 2020'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '09:29'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered '29 Oct 2020 09:29'	System	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '36' C	Andrea Wendrow (b) (4)	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Other (Other)'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'ear'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '88'	Andrea Wendrow (b) (4)	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered 'bpm'	System	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '12'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered 'breaths/min'	System	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '117'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered 'mmHg'	System	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '73'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered 'mmHg'	System	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User accepted default value 'Post-Dose (POSTDOSE)'	Andrea Wendrow (b) (4) (b) (4)	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Oct 2020 21:47:33
User entered 'Yes (Y)' reason for change: Data Entry Error	System	29 Oct 2020 21:47:33
User opened query 'Data is required. Please complete.' (Site from System).	Andrea Wendrow (b) (4)	29 Oct 2020 21:47:33
User entered empty.	(b) (4)	
	System	29 Oct 2020 21:47:27
	Andrea Wendrow (b) (4)	29 Oct 2020 21:47:27
	(b) (4)	

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '29 Oct 2020'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '11:02'	Andrea Wendrow (b) (4)	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered '29 Oct 2020 11:02'	System	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '97' F	Andrea Wendrow (b) (4)	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Other (Other)'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'ear'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '75'	Andrea Wendrow (b) (4)	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered 'bpm'	System	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '20'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered 'breaths/min'	System	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '111'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered 'mmHg'	System	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '72'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered 'mmHg'	System	29 Oct 2020 21:47:27

US3492281

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 21:47:49

US3492281

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '29 Oct 2020'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 21:47:49

US3492281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:53:00

US3492281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:53:00

US3492281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:53:00

US3492281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered 'MRNA-1273 OR PLACEBO'	System	29 Oct 2020 15:53:00

US3492281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:53:00

US3492281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '10:48'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:53:00

US3492281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered '29 Oct 2020 10:48'	System	29 Oct 2020 15:53:00

US3492281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:53:00

US3492281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered 'ONCE'	System	29 Oct 2020 15:53:00

US3492281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered 'INTRAMUSCULAR'	System	29 Oct 2020 15:53:00

US3492281

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 21:48:32

US3492281

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '29 Oct 2020'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 21:48:32

US3492281

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '09:50'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 21:48:32

US3492281

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered '29 Oct 2020 09:50'	System	29 Oct 2020 21:48:32

US3492281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:03:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '29 Oct 2020'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 21:49:11

US3492281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:03:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Andrea Wendrow (b) (4)	29 Oct 2020 21:49:11

US3492281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:03:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	29 Oct 2020 21:49:11

US3492281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:03:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '09:57'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 21:49:11

US3492281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered '29 Oct 2020 09:57'	System	29 Oct 2020 21:49:11

US3492281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:03:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Andrea Wendrow (b) (4)	29 Oct 2020 21:49:11

US3492281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:03:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 21:49:11

US3492281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:03:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered empty.	Andrea Wendrow (b) (4)	29 Oct 2020 21:49:11

US3492281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered empty.	System	29 Oct 2020 21:49:11

US3492281

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:43:45

US3492281

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered 'I'	System	29 Oct 2020 16:43:45

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	29 Oct 2020 15:53:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-29T11:08:09', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '66342269-967f-4d53-8371-55559516ffd0' User entered 'Yes (Y)'	System	29 Oct 2020 16:08:24
	System	29 Oct 2020 16:08:24

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-29T11:08:13', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '66342269-967f-4d53-8371-55559516ffd0' User entered '97.0'	System	29 Oct 2020 16:08:24
	System	29 Oct 2020 16:08:24

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-29T11:08:16', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '66342269-967f-4d53-8371-55559516ffd0'	System	29 Oct 2020 16:08:24
User entered 'No (N)'	System	29 Oct 2020 16:08:24

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-29T11:08:19', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '66342269-967f-4d53-8371-55559516ffd0' User entered '29 Oct 2020 11:08'	System	29 Oct 2020 16:08:24
	System	29 Oct 2020 16:08:24

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '29 Oct 2020 11:08'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '29 Oct 2020 13:38'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	29 Oct 2020 15:53:00
User entered 'Day 1, after vaccination (at home)'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T01:16:18', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '6e7d660b-0b06-4fb5-a030-17c300c83204' User entered 'Yes (Y)'	System	30 Oct 2020 06:16:33
	System	30 Oct 2020 06:16:33

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T01:16:25', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '6e7d660b-0b06-4fb5-a030-17c300c83204' User entered '97.3'	System	30 Oct 2020 06:16:33
	System	30 Oct 2020 06:16:33

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T01:16:28', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '6e7d660b-0b06-4fb5-a030-17c300c83204' User entered 'No (N)'	System	30 Oct 2020 06:16:33
	System	30 Oct 2020 06:16:33

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T01:16:31', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '6e7d660b-0b06-4fb5-a030-17c300c83204' User entered '30 Oct 2020 01:16'	System	30 Oct 2020 06:16:33
	System	30 Oct 2020 06:16:33

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '29 Oct 2020 14:33'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '30 Oct 2020 11:59'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	29 Oct 2020 15:53:00
User entered 'Day 2'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T23:59:16', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '80bdba49-222a-45c5-b5bb-d90a66eb4b65' User entered 'Yes (Y)'	System	31 Oct 2020 04:59:35
	System	31 Oct 2020 04:59:35

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T23:59:23', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '80bdba49-222a-45c5-b5bb-d90a66eb4b65' User entered '98.0'	System	31 Oct 2020 04:59:35
	System	31 Oct 2020 04:59:35

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T23:59:25', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '80bdba49-222a-45c5-b5bb-d90a66eb4b65'	System	31 Oct 2020 04:59:35
User entered 'No (N)'	System	31 Oct 2020 04:59:35

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T23:59:29', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '80bdba49-222a-45c5-b5bb-d90a66eb4b65' User entered '30 Oct 2020 23:59'	System	31 Oct 2020 04:59:35
	System	31 Oct 2020 04:59:35

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '30 Oct 2020 12:00'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '31 Oct 2020 11:59'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	29 Oct 2020 15:53:00
User entered 'Day 3'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:36

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-01T09:29:21', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '524ae786-9b05-4f23-8c87-c197dd8fa35c' User entered 'Yes (Y)'	System	01 Nov 2020 15:29:40
	System	01 Nov 2020 15:29:40

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-01T09:29:29', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '524ae786-9b05-4f23-8c87-c197dd8fa35c' User entered '97.3'	System	01 Nov 2020 15:29:40
	System	01 Nov 2020 15:29:40

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-01T09:29:33', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '524ae786-9b05-4f23-8c87-c197dd8fa35c' User entered 'No (N)'	System	01 Nov 2020 15:29:40
	System	01 Nov 2020 15:29:40

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-01T09:29:38', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '524ae786-9b05-4f23-8c87-c197dd8fa35c' User entered '01 Nov 2020 09:29'	System	01 Nov 2020 15:29:40
	System	01 Nov 2020 15:29:40

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '31 Oct 2020 12:00'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '01 Nov 2020 11:59'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	29 Oct 2020 15:53:00
User entered 'Day 4'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T02:51:41', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'b8587ab2-cf75-4b4d-88ed-6ecc51c40d0e' User entered 'Yes (Y)'	System	02 Nov 2020 08:51:55
	System	02 Nov 2020 08:51:55

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T02:51:47', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'b8587ab2-cf75-4b4d-88ed-6ecc51c40d0e' User entered '97.6'	System	02 Nov 2020 08:51:55
	System	02 Nov 2020 08:51:55

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T02:51:50', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'b8587ab2-cf75-4b4d-88ed-6ecc51c40d0e' User entered 'No (N)'	System	02 Nov 2020 08:51:55
	System	02 Nov 2020 08:51:55

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T02:51:53', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'b8587ab2-cf75-4b4d-88ed-6ecc51c40d0e' User entered '02 Nov 2020 02:51'	System	02 Nov 2020 08:51:55
	System	02 Nov 2020 08:51:55

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '01 Nov 2020 12:00'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '02 Nov 2020 11:59'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	29 Oct 2020 15:53:00
User entered 'Day 5'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:36

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T15:23:12', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '4855cb41-5d3c-4861-8030-b946fe5fcf27'	System	02 Nov 2020 21:23:25
User entered 'Yes (Y)'	System	02 Nov 2020 21:23:25

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T15:23:16', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '4855cb41-5d3c-4861-8030-b946fe5fcf27' User entered '98.2'	System	02 Nov 2020 21:23:25
	System	02 Nov 2020 21:23:25

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T15:23:19', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '4855cb41-5d3c-4861-8030-b946fe5fcf27'	System	02 Nov 2020 21:23:25
User entered 'No (N)'	System	02 Nov 2020 21:23:25

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T15:23:21', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '4855cb41-5d3c-4861-8030-b946fe5fcf27' User entered '02 Nov 2020 15:23'	System	02 Nov 2020 21:23:25
	System	02 Nov 2020 21:23:25

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '02 Nov 2020 12:00'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '03 Nov 2020 11:59'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	29 Oct 2020 15:53:00
User entered 'Day 6'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:36

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-03T12:01:27', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'ec295a6a-b1da-4f17-9ac7-889607412c71' User entered 'Yes (Y)'	System	03 Nov 2020 18:01:40
	System	03 Nov 2020 18:01:40

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-03T12:01:31', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'ec295a6a-b1da-4f17-9ac7-889607412c71' User entered '96.0'	System	03 Nov 2020 18:01:40
	System	03 Nov 2020 18:01:40

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-03T12:01:33', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'ec295a6a-b1da-4f17-9ac7-889607412c71' User entered 'No (N)'	System	03 Nov 2020 18:01:40
	System	03 Nov 2020 18:01:40

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-03T12:01:36', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'ec295a6a-b1da-4f17-9ac7-889607412c71' User entered '03 Nov 2020 12:01'	System	03 Nov 2020 18:01:40
	System	03 Nov 2020 18:01:40

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '03 Nov 2020 12:00'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '04 Nov 2020 11:59'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	29 Oct 2020 15:53:00
User entered 'Day 7'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:36

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-04T12:00:53', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'afad89a6-34ac-4c5a-a5bb-3afb507e7851' User entered 'Yes (Y)'	System	04 Nov 2020 18:01:17
	System	04 Nov 2020 18:01:17

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-04T12:01:03', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'afad89a6-34ac-4c5a-a5bb-3afb507e7851' User entered '97.1'	System	04 Nov 2020 18:01:17
	System	04 Nov 2020 18:01:17

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-04T12:01:06', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'afad89a6-34ac-4c5a-a5bb-3afb507e7851' User entered 'No (N)'	System	04 Nov 2020 18:01:17
	System	04 Nov 2020 18:01:17

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-04T12:01:08', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'afad89a6-34ac-4c5a-a5bb-3afb507e7851' User entered '04 Nov 2020 12:01'	System	04 Nov 2020 18:01:17
	System	04 Nov 2020 18:01:17

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '04 Nov 2020 12:00'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '05 Nov 2020 11:59'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	29 Oct 2020 15:53:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-29T11:08:29', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '205af74c-ca1c-4bf3-9260-461fb6c6298b' User entered 'None (1)'	System	29 Oct 2020 16:08:44
	System	29 Oct 2020 16:08:44

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-29T11:08:31', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '205af74c-ca1c-4bf3-9260-461fb6c6298b' User entered 'No (N)'	System	29 Oct 2020 16:08:44
	System	29 Oct 2020 16:08:44

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-29T11:08:33', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '205af74c-ca1c-4bf3-9260-461fb6c6298b' User entered 'No (N)'	System	29 Oct 2020 16:08:44
	System	29 Oct 2020 16:08:44

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-29T11:08:36', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '205af74c-ca1c-4bf3-9260-461fb6c6298b' User entered 'None (1)'	System	29 Oct 2020 16:08:44
	System	29 Oct 2020 16:08:44

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-29T11:08:39', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '205af74c-ca1c-4bf3-9260-461fb6c6298b' User entered '29 Oct 2020 11:08'	System	29 Oct 2020 16:08:44
	System	29 Oct 2020 16:08:44

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '29 Oct 2020 11:08'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '29 Oct 2020 13:38'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	29 Oct 2020 15:53:00
User entered 'Day 1, after vaccination (at home)'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T01:16:35', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '3201b110-6a23-466e-a475-a4c052847830' User entered 'None (1)'	System	30 Oct 2020 06:16:46
	System	30 Oct 2020 06:16:46

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T01:16:38', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '3201b110-6a23-466e-a475-a4c052847830' User entered 'No (N)'	System	30 Oct 2020 06:16:46
	System	30 Oct 2020 06:16:46

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T01:16:40', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '3201b110-6a23-466e-a475-a4c052847830' User entered 'No (N)'	System	30 Oct 2020 06:16:46
	System	30 Oct 2020 06:16:46

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T01:16:41', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '3201b110-6a23-466e-a475-a4c052847830' User entered 'None (1)'	System	30 Oct 2020 06:16:46
	System	30 Oct 2020 06:16:46

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T01:16:44', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '3201b110-6a23-466e-a475-a4c052847830' User entered '30 Oct 2020 01:16'	System	30 Oct 2020 06:16:46
	System	30 Oct 2020 06:16:46

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '29 Oct 2020 14:33'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '30 Oct 2020 11:59'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	29 Oct 2020 15:53:00
User entered 'Day 2'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T23:59:32', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '18e1be5c-75eb-4c9b-8ed9-37072339d78d' User entered 'None (1)'	System	31 Oct 2020 04:59:48
	System	31 Oct 2020 04:59:48

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T23:59:36', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '18e1be5c-75eb-4c9b-8ed9-37072339d78d' User entered 'No (N)'	System	31 Oct 2020 04:59:48
	System	31 Oct 2020 04:59:48

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T23:59:39', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '18e1be5c-75eb-4c9b-8ed9-37072339d78d' User entered 'No (N)'	System	31 Oct 2020 04:59:48
	System	31 Oct 2020 04:59:48

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T23:59:41', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '18e1be5c-75eb-4c9b-8ed9-37072339d78d' User entered 'None (1)'	System	31 Oct 2020 04:59:48
	System	31 Oct 2020 04:59:48

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T23:59:44', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '18e1be5c-75eb-4c9b-8ed9-37072339d78d' User entered '30 Oct 2020 23:59'	System	31 Oct 2020 04:59:48
	System	31 Oct 2020 04:59:48

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '30 Oct 2020 12:00'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '31 Oct 2020 11:59'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	29 Oct 2020 15:53:00
User entered 'Day 3'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-01T09:29:42', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'f40ddd80-f3af-4fce-b55a-814ca28e91d6'	System	01 Nov 2020 15:29:57
User entered 'None (1)'	System	01 Nov 2020 15:29:57

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-01T09:29:46', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'f40ddd80-f3af-4fce-b55a-814ca28e91d6' User entered 'No (N)'	System	01 Nov 2020 15:29:57
	System	01 Nov 2020 15:29:57

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-01T09:29:50', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'f40ddd80-f3af-4fce-b55a-814ca28e91d6' User entered 'No (N)'	System	01 Nov 2020 15:29:57
	System	01 Nov 2020 15:29:57

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-01T09:29:52', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'f40ddd80-f3af-4fce-b55a-814ca28e91d6'	System	01 Nov 2020 15:29:57
User entered 'None (1)'	System	01 Nov 2020 15:29:57

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-01T09:29:55', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'f40ddd80-f3af-4fce-b55a-814ca28e91d6' User entered '01 Nov 2020 09:29'	System	01 Nov 2020 15:29:57
	System	01 Nov 2020 15:29:57

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '31 Oct 2020 12:00'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '01 Nov 2020 11:59'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	29 Oct 2020 15:53:00
User entered 'Day 4'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T02:51:56', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '35a73f4b-76bf-4fb4-ae28-a62a0f56c31c' User entered 'None (1)'	System	02 Nov 2020 08:52:08
	System	02 Nov 2020 08:52:08

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T02:52:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '35a73f4b-76bf-4fb4-ae28-a62a0f56c31c' User entered 'No (N)'	System	02 Nov 2020 08:52:08
	System	02 Nov 2020 08:52:08

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T02:52:02', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '35a73f4b-76bf-4fb4-ae28-a62a0f56c31c' User entered 'No (N)'	System	02 Nov 2020 08:52:08
	System	02 Nov 2020 08:52:08

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T02:52:04', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '35a73f4b-76bf-4fb4-ae28-a62a0f56c31c' User entered 'None (1)'	System	02 Nov 2020 08:52:08
	System	02 Nov 2020 08:52:08

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T02:52:07', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '35a73f4b-76bf-4fb4-ae28-a62a0f56c31c' User entered '02 Nov 2020 02:52'	System	02 Nov 2020 08:52:08
	System	02 Nov 2020 08:52:08

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '01 Nov 2020 12:00'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '02 Nov 2020 11:59'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	29 Oct 2020 15:53:00
User entered 'Day 5'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T15:23:24', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '2af48e65-3b55-4263-880f-20d276f9e508'	System	02 Nov 2020 21:23:36
User entered 'None (1)'	System	02 Nov 2020 21:23:36

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T15:23:26', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '2af48e65-3b55-4263-880f-20d276f9e508'	System	02 Nov 2020 21:23:36
User entered 'No (N)'	System	02 Nov 2020 21:23:36

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T15:23:28', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '2af48e65-3b55-4263-880f-20d276f9e508'	System	02 Nov 2020 21:23:36
User entered 'No (N)'	System	02 Nov 2020 21:23:36

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T15:23:30', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '2af48e65-3b55-4263-880f-20d276f9e508'	System	02 Nov 2020 21:23:36
User entered 'None (1)'	System	02 Nov 2020 21:23:36

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T15:23:32', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '2af48e65-3b55-4263-880f-20d276f9e508' User entered '02 Nov 2020 15:23'	System	02 Nov 2020 21:23:36
	System	02 Nov 2020 21:23:36

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '02 Nov 2020 12:00'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '03 Nov 2020 11:59'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	29 Oct 2020 15:53:00
User entered 'Day 6'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-03T12:01:39', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '7b43892d-55c7-4b3c-8a5f-5f50febb0452'	System	03 Nov 2020 18:01:53
User entered 'None (1)'	System	03 Nov 2020 18:01:53

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-03T12:01:41', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '7b43892d-55c7-4b3c-8a5f-5f50febb0452' User entered 'No (N)'	System	03 Nov 2020 18:01:53
	System	03 Nov 2020 18:01:53

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-03T12:01:42', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '7b43892d-55c7-4b3c-8a5f-5f50febb0452' User entered 'No (N)'	System	03 Nov 2020 18:01:53
	System	03 Nov 2020 18:01:53

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-03T12:01:44', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '7b43892d-55c7-4b3c-8a5f-5f50febb0452'	System	03 Nov 2020 18:01:53
User entered 'None (1)'	System	03 Nov 2020 18:01:53

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-03T12:01:51', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '7b43892d-55c7-4b3c-8a5f-5f50febb0452' User entered '03 Nov 2020 12:01'	System	03 Nov 2020 18:01:53
	System	03 Nov 2020 18:01:53

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '03 Nov 2020 12:00'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '04 Nov 2020 11:59'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	29 Oct 2020 15:53:00
User entered 'Day 7'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-04T12:01:11', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'cac3666d-4382-4451-b520-13d922bf5e7f' User entered 'None (1)'	System	04 Nov 2020 18:01:23
	System	04 Nov 2020 18:01:23

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-04T12:01:14', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'cac3666d-4382-4451-b520-13d922bf5e7f' User entered 'No (N)'	System	04 Nov 2020 18:01:23
	System	04 Nov 2020 18:01:23

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-04T12:01:16', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'cac3666d-4382-4451-b520-13d922bf5e7f' User entered 'No (N)'	System	04 Nov 2020 18:01:23
	System	04 Nov 2020 18:01:23

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-04T12:01:18', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'cac3666d-4382-4451-b520-13d922bf5e7f' User entered 'None (1)'	System	04 Nov 2020 18:01:23
	System	04 Nov 2020 18:01:23

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-04T12:01:20', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'cac3666d-4382-4451-b520-13d922bf5e7f' User entered '04 Nov 2020 12:01'	System	04 Nov 2020 18:01:23
	System	04 Nov 2020 18:01:23

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '04 Nov 2020 12:00'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '05 Nov 2020 11:59'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	29 Oct 2020 15:53:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-29T11:08:44', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '606d8dfb-da01-4b1c-bc05-18ee508c4c13' User entered 'None (0)'	System	29 Oct 2020 16:09:04
	System	29 Oct 2020 16:09:04

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-29T11:08:46', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '606d8dfb-da01-4b1c-bc05-18ee508c4c13' User entered 'None (0)'	System	29 Oct 2020 16:09:04
	System	29 Oct 2020 16:09:04

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-29T11:08:48', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '606d8dfb-da01-4b1c-bc05-18ee508c4c13' User entered 'None (0)'	System	29 Oct 2020 16:09:04
	System	29 Oct 2020 16:09:04

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-29T11:08:50', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '606d8dfb-da01-4b1c-bc05-18ee508c4c13' User entered 'None (0)'	System	29 Oct 2020 16:09:04
	System	29 Oct 2020 16:09:04

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-29T11:08:52', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '606d8dfb-da01-4b1c-bc05-18ee508c4c13' User entered 'None (0)'	System	29 Oct 2020 16:09:04
	System	29 Oct 2020 16:09:04

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-29T11:08:54', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '606d8dfb-da01-4b1c-bc05-18ee508c4c13' User entered 'None (0)'	System	29 Oct 2020 16:09:04
	System	29 Oct 2020 16:09:04

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-29T11:08:58', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '606d8dfb-da01-4b1c-bc05-18ee508c4c13' User entered 'No (N)'	System	29 Oct 2020 16:09:04
	System	29 Oct 2020 16:09:04

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-29T11:09:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '606d8dfb-da01-4b1c-bc05-18ee508c4c13' User entered '29 Oct 2020 11:09'	System	29 Oct 2020 16:09:04
	System	29 Oct 2020 16:09:04

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '29 Oct 2020 11:08'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '29 Oct 2020 13:38'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	29 Oct 2020 15:53:00
User entered 'Day 1, after vaccination (at home)'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T01:16:48', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'b699b2c9-20db-4e27-a0ee-958f494c4caf' User entered 'None (0)'	System	30 Oct 2020 06:17:08
	System	30 Oct 2020 06:17:08

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T01:16:49', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'b699b2c9-20db-4e27-a0ee-958f494c4caf' User entered 'None (0)'	System	30 Oct 2020 06:17:08
	System	30 Oct 2020 06:17:08

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T01:16:51', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'b699b2c9-20db-4e27-a0ee-958f494c4caf' User entered 'None (0)'	System	30 Oct 2020 06:17:08
	System	30 Oct 2020 06:17:08

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T01:16:53', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'b699b2c9-20db-4e27-a0ee-958f494c4caf' User entered 'None (0)'	System	30 Oct 2020 06:17:08
	System	30 Oct 2020 06:17:08

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T01:16:54', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'b699b2c9-20db-4e27-a0ee-958f494c4caf' User entered 'None (0)'	System	30 Oct 2020 06:17:08
	System	30 Oct 2020 06:17:08

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T01:16:56', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'b699b2c9-20db-4e27-a0ee-958f494c4caf' User entered 'None (0)'	System	30 Oct 2020 06:17:08
	System	30 Oct 2020 06:17:08

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T01:17:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'b699b2c9-20db-4e27-a0ee-958f494c4caf' User entered 'No (N)'	System	30 Oct 2020 06:17:08
	System	30 Oct 2020 06:17:08

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T01:17:04', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'b699b2c9-20db-4e27-a0ee-958f494c4caf' User entered '30 Oct 2020 01:17'	System	30 Oct 2020 06:17:08
	System	30 Oct 2020 06:17:08

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '29 Oct 2020 14:33'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '30 Oct 2020 11:59'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	29 Oct 2020 15:53:00
User entered 'Day 2'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T23:59:48', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '18b2e1ae-529f-4259-849b-dc32bde125ed' User entered 'None (0)'	System	31 Oct 2020 05:00:06
	System	31 Oct 2020 05:00:06

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T23:59:50', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '18b2e1ae-529f-4259-849b-dc32bde125ed' User entered 'None (0)'	System	31 Oct 2020 05:00:06
	System	31 Oct 2020 05:00:06

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T23:59:52', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '18b2e1ae-529f-4259-849b-dc32bde125ed' User entered 'None (0)'	System	31 Oct 2020 05:00:06
	System	31 Oct 2020 05:00:06

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T23:59:54', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '18b2e1ae-529f-4259-849b-dc32bde125ed' User entered 'None (0)'	System	31 Oct 2020 05:00:06
	System	31 Oct 2020 05:00:06

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T23:59:56', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '18b2e1ae-529f-4259-849b-dc32bde125ed' User entered 'None (0)'	System	31 Oct 2020 05:00:06
	System	31 Oct 2020 05:00:06

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T23:59:57', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '18b2e1ae-529f-4259-849b-dc32bde125ed' User entered 'None (0)'	System	31 Oct 2020 05:00:06
	System	31 Oct 2020 05:00:06

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-30T23:59:59', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '18b2e1ae-529f-4259-849b-dc32bde125ed' User entered 'No (N)'	System	31 Oct 2020 05:00:06
	System	31 Oct 2020 05:00:06

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-10-31T00:00:02', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '18b2e1ae-529f-4259-849b-dc32bde125ed' User entered '31 Oct 2020 00:00'	System	31 Oct 2020 05:00:06
	System	31 Oct 2020 05:00:06

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '30 Oct 2020 12:00'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '31 Oct 2020 11:59'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	29 Oct 2020 15:53:00
User entered 'Day 3'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-01T09:29:58', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'f032b764-f5d1-47f3-8c4f-a852fd4412e4' User entered 'None (0)'	System	01 Nov 2020 15:30:15
	System	01 Nov 2020 15:30:15

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-01T09:30:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'f032b764-f5d1-47f3-8c4f-a852fd4412e4' User entered 'None (0)'	System	01 Nov 2020 15:30:15
	System	01 Nov 2020 15:30:15

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-01T09:30:01', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'f032b764-f5d1-47f3-8c4f-a852fd4412e4' User entered 'None (0)'	System	01 Nov 2020 15:30:15
	System	01 Nov 2020 15:30:15

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-01T09:30:03', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'f032b764-f5d1-47f3-8c4f-a852fd4412e4' User entered 'None (0)'	System	01 Nov 2020 15:30:15
	System	01 Nov 2020 15:30:15

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-01T09:30:04', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'f032b764-f5d1-47f3-8c4f-a852fd4412e4' User entered 'None (0)'	System	01 Nov 2020 15:30:15
	System	01 Nov 2020 15:30:15

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-01T09:30:06', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'f032b764-f5d1-47f3-8c4f-a852fd4412e4' User entered 'None (0)'	System	01 Nov 2020 15:30:15
	System	01 Nov 2020 15:30:15

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-01T09:30:08', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'f032b764-f5d1-47f3-8c4f-a852fd4412e4' User entered 'No (N)'	System	01 Nov 2020 15:30:15
	System	01 Nov 2020 15:30:15

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-01T09:30:11', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'f032b764-f5d1-47f3-8c4f-a852fd4412e4' User entered '01 Nov 2020 09:30'	System	01 Nov 2020 15:30:15
	System	01 Nov 2020 15:30:15

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '31 Oct 2020 12:00'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '01 Nov 2020 11:59'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	29 Oct 2020 15:53:00
User entered 'Day 4'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T02:52:10', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '30a4eb94-675e-49d2-9858-81e47a686eb2' User entered 'None (0)'	System	02 Nov 2020 08:52:26
	System	02 Nov 2020 08:52:26

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T02:52:12', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '30a4eb94-675e-49d2-9858-81e47a686eb2' User entered 'None (0)'	System	02 Nov 2020 08:52:26
	System	02 Nov 2020 08:52:26

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T02:52:13', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '30a4eb94-675e-49d2-9858-81e47a686eb2' User entered 'None (0)'	System	02 Nov 2020 08:52:26
	System	02 Nov 2020 08:52:26

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T02:52:14', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '30a4eb94-675e-49d2-9858-81e47a686eb2' User entered 'None (0)'	System	02 Nov 2020 08:52:26
	System	02 Nov 2020 08:52:26

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T02:52:16', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '30a4eb94-675e-49d2-9858-81e47a686eb2' User entered 'None (0)'	System	02 Nov 2020 08:52:26
	System	02 Nov 2020 08:52:26

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T02:52:17', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '30a4eb94-675e-49d2-9858-81e47a686eb2' User entered 'None (0)'	System	02 Nov 2020 08:52:26
	System	02 Nov 2020 08:52:26

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T02:52:20', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '30a4eb94-675e-49d2-9858-81e47a686eb2' User entered 'No (N)'	System	02 Nov 2020 08:52:26
	System	02 Nov 2020 08:52:26

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T02:52:22', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '30a4eb94-675e-49d2-9858-81e47a686eb2' User entered '02 Nov 2020 02:52'	System	02 Nov 2020 08:52:26
	System	02 Nov 2020 08:52:26

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '01 Nov 2020 12:00'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '02 Nov 2020 11:59'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	29 Oct 2020 15:53:00
User entered 'Day 5'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T15:23:35', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '6d95fe13-a020-4100-81ba-7e9d0bca30e2' User entered 'None (0)'	System	02 Nov 2020 21:23:51
	System	02 Nov 2020 21:23:51

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T15:23:37', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '6d95fe13-a020-4100-81ba-7e9d0bca30e2' User entered 'None (0)'	System	02 Nov 2020 21:23:51
	System	02 Nov 2020 21:23:51

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T15:23:38', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '6d95fe13-a020-4100-81ba-7e9d0bca30e2' User entered 'None (0)'	System	02 Nov 2020 21:23:51
	System	02 Nov 2020 21:23:51

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T15:23:40', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '6d95fe13-a020-4100-81ba-7e9d0bca30e2' User entered 'None (0)'	System	02 Nov 2020 21:23:51
	System	02 Nov 2020 21:23:51

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T15:23:41', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '6d95fe13-a020-4100-81ba-7e9d0bca30e2' User entered 'None (0)'	System	02 Nov 2020 21:23:51
	System	02 Nov 2020 21:23:51

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T15:23:43', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '6d95fe13-a020-4100-81ba-7e9d0bca30e2' User entered 'None (0)'	System	02 Nov 2020 21:23:51
	System	02 Nov 2020 21:23:51

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T15:23:45', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '6d95fe13-a020-4100-81ba-7e9d0bca30e2' User entered 'No (N)'	System	02 Nov 2020 21:23:51
	System	02 Nov 2020 21:23:51

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-02T15:23:48', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '6d95fe13-a020-4100-81ba-7e9d0bca30e2' User entered '02 Nov 2020 15:23'	System	02 Nov 2020 21:23:51
	System	02 Nov 2020 21:23:51

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '02 Nov 2020 12:00'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '03 Nov 2020 11:59'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	29 Oct 2020 15:53:00
User entered 'Day 6'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-03T12:01:53', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'fe37e040-ade9-4410-9473-2ef38e53372b' User entered 'None (0)'	System	03 Nov 2020 18:02:11
	System	03 Nov 2020 18:02:11

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-03T12:01:55', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'fe37e040-ade9-4410-9473-2ef38e53372b' User entered 'None (0)'	System	03 Nov 2020 18:02:11
	System	03 Nov 2020 18:02:11

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-03T12:01:57', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'fe37e040-ade9-4410-9473-2ef38e53372b' User entered 'None (0)'	System	03 Nov 2020 18:02:11
	System	03 Nov 2020 18:02:11

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-03T12:01:58', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'fe37e040-ade9-4410-9473-2ef38e53372b' User entered 'None (0)'	System	03 Nov 2020 18:02:11
	System	03 Nov 2020 18:02:11

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-03T12:02:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'fe37e040-ade9-4410-9473-2ef38e53372b' User entered 'None (0)'	System	03 Nov 2020 18:02:11
	System	03 Nov 2020 18:02:11

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-03T12:02:01', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'fe37e040-ade9-4410-9473-2ef38e53372b' User entered 'None (0)'	System	03 Nov 2020 18:02:11
	System	03 Nov 2020 18:02:11

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-03T12:02:03', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'fe37e040-ade9-4410-9473-2ef38e53372b' User entered 'No (N)'	System	03 Nov 2020 18:02:11
	System	03 Nov 2020 18:02:11

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-03T12:02:05', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'fe37e040-ade9-4410-9473-2ef38e53372b' User entered '03 Nov 2020 12:02'	System	03 Nov 2020 18:02:11
	System	03 Nov 2020 18:02:11

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '03 Nov 2020 12:00'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '04 Nov 2020 11:59'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
Data entry locked.	System	29 Oct 2020 15:53:00
User entered 'Day 7'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-04T12:01:26', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '5d1d2689-3cb5-45b4-a638-1cf52d50a4d8' User entered 'None (0)'	System	04 Nov 2020 18:02:01
	System	04 Nov 2020 18:02:01

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-04T12:01:28', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '5d1d2689-3cb5-45b4-a638-1cf52d50a4d8' User entered 'None (0)'	System	04 Nov 2020 18:02:01
	System	04 Nov 2020 18:02:01

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-04T12:01:30', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '5d1d2689-3cb5-45b4-a638-1cf52d50a4d8' User entered 'None (0)'	System	04 Nov 2020 18:02:01
	System	04 Nov 2020 18:02:01

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-04T12:01:31', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '5d1d2689-3cb5-45b4-a638-1cf52d50a4d8' User entered 'None (0)'	System	04 Nov 2020 18:02:01
	System	04 Nov 2020 18:02:01

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-04T12:01:37', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '5d1d2689-3cb5-45b4-a638-1cf52d50a4d8' User entered 'None (0)'	System	04 Nov 2020 18:02:01
	System	04 Nov 2020 18:02:01

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-04T12:01:51', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '5d1d2689-3cb5-45b4-a638-1cf52d50a4d8' User entered 'None (0)'	System	04 Nov 2020 18:02:01
	System	04 Nov 2020 18:02:01

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:36

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 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-04T12:01:53', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '5d1d2689-3cb5-45b4-a638-1cf52d50a4d8' User entered 'No (N)'	System	04 Nov 2020 18:02:01
	System	04 Nov 2020 18:02:01

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-04T12:01:55', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '5d1d2689-3cb5-45b4-a638-1cf52d50a4d8' User entered '04 Nov 2020 12:01'	System	04 Nov 2020 18:02:01
	System	04 Nov 2020 18:02:01

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '04 Nov 2020 12:00'	System	29 Oct 2020 15:53:00

US3492281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:02:46
User entered '05 Nov 2020 11:59'	System	29 Oct 2020 15:53:00

US3492281

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:33:43

US3492281

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '5 Nov 2020'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:33:43

US3492281

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:33:43

US3492281

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:33:43

US3492281

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:33:49

US3492281

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User entered 'I'	System	06 Nov 2020 15:33:49

US3492281

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann	17 Nov 2020 20:30:34
	(b) (4)	

US3492281

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '12 Nov 2020'	(b) (4) Lorna Sanchez McCann	17 Nov 2020 20:30:34
	(b) (4)	

US3492281

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lorna Sanchez McCann (b) (4)	17 Nov 2020 20:30:34

US3492281

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered empty.	Lorna Sanchez McCann (b) (4)	17 Nov 2020 20:30:34

US3492281

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann	17 Nov 2020 20:40:02
	(b) (4)	

US3492281

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User entered 'I'	System	17 Nov 2020 20:40:02

US3492281

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann	20 Nov 2020 16:13:47
	(b) (4)	

US3492281

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '19 Nov 2020' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 16:13:54
User entered '20 Nov 2020'	Lorna Sanchez McCann	20 Nov 2020 16:13:47
	(b) (4)	

US3492281

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lorna Sanchez McCann (b) (4)	20 Nov 2020 16:13:47

US3492281

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered empty.	Lorna Sanchez McCann (b) (4)	20 Nov 2020 16:13:47

US3492281

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann	20 Nov 2020 16:14:02
	(b) (4)	

US3492281

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User entered 'I'	System	20 Nov 2020 16:14:02

US3492281

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann	25 Nov 2020 15:09:14
	(b) (4)	

US3492281

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '25 Nov 2020'	(b) (4) Lorna Sanchez McCann	25 Nov 2020 15:09:14
	(b) (4)	

US3492281

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Clinic (Clinic)'	(b) (4) Lorna Sanchez McCann (b) (4)	25 Nov 2020 15:09:14

US3492281

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered 'VISIT3'	System	25 Nov 2020 15:09:14

US3492281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann	25 Nov 2020 15:10:00
	(b) (4)	

US3492281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '25 Nov 2020'	(b) (4) Lorna Sanchez McCann	25 Nov 2020 15:10:00
	(b) (4)	

US3492281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '09:05'	(b) (4) Lorna Sanchez McCann	25 Nov 2020 15:10:00
	(b) (4)	

US3492281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered '25 Nov 2020 09:05'	System	25 Nov 2020 15:10:00

US3492281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '97.6' F	Lorna Sanchez McCann (b) (4)	25 Nov 2020 15:10:00

US3492281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Other (Other)'	Lorna Sanchez McCann (b) (4)	25 Nov 2020 15:10:00

US3492281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'tympanic'	(b) (4) Lorna Sanchez McCann (b) (4)	25 Nov 2020 15:10:00

US3492281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '87'	Lorna Sanchez McCann (b) (4)	25 Nov 2020 15:10:00

US3492281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered 'bpm'	System	25 Nov 2020 15:10:00

US3492281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '18'	Lorna Sanchez McCann (b) (4)	25 Nov 2020 15:10:00

US3492281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered 'breaths/min'	System	25 Nov 2020 15:10:00

US3492281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '132'	Lorna Sanchez McCann (b) (4)	25 Nov 2020 15:10:00

US3492281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered 'mmHg'	System	25 Nov 2020 15:10:00

US3492281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '87'	Lorna Sanchez McCann (b) (4)	25 Nov 2020 15:10:00

US3492281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered 'mmHg'	System	25 Nov 2020 15:10:00

US3492281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40

US3492281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40

US3492281

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann	25 Nov 2020 15:10:19
	(b) (4)	

US3492281

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '25 Nov 2020'	Lorna Sanchez McCann (b) (4)	25 Nov 2020 15:10:19

US3492281

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	25 Nov 2020 15:16:24

US3492281

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '25 Nov 2020'	Gizelle Alvarez (b) (4)	25 Nov 2020 15:16:24

US3492281

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '09:12'	Gizelle Alvarez (b) (4)	25 Nov 2020 15:16:24

US3492281

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered '25 Nov 2020 09:12'	System	25 Nov 2020 15:16:24

US3492281

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) Gizelle Alvarez (b) (4)	25 Nov 2020 15:16:29

US3492281

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:40
User entered 'I'	System	25 Nov 2020 15:16:29

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-28T14:49:58', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '06fe7431-d31f-4c35-98c6-c986f399c578'	System	28 Nov 2020 20:50:25
User entered 'No (N)'	System	28 Nov 2020 20:50:25

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Have you been exposed to someone with 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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-28T14:50:05', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '06fe7431-d31f-4c35-98c6-c986f399c578'	System	28 Nov 2020 20:50:25
User entered 'Yes (Y)'	System	28 Nov 2020 20:50:25

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-28T14:50:09', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '06fe7431-d31f-4c35-98c6-c986f399c578'	System	28 Nov 2020 20:50:25
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Nov 2020 20:50:25

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-11-28T14:50:16', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '06fe7431-d31f-4c35-98c6-c986f399c578' User entered '28 Nov 2020 14:50:16'	System	28 Nov 2020 20:50:25
	System	28 Nov 2020 20:50:25

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-12-05T06:27:29', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '5c584a41-87f2-41d7-a0c6-31d1e92b3897' User entered 'No (N)'	System	05 Dec 2020 12:27:42
	System	05 Dec 2020 12:27:42

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Have you been exposed to someone with 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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-12-05T06:27:35', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '5c584a41-87f2-41d7-a0c6-31d1e92b3897'	System	05 Dec 2020 12:27:42
User entered 'No (N)'	System	05 Dec 2020 12:27:42

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-12-05T06:27:39', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '5c584a41-87f2-41d7-a0c6-31d1e92b3897' User entered '05 Dec 2020 06:27:39'	System	05 Dec 2020 12:27:42
	System	05 Dec 2020 12:27:42

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-12-13T10:05:11', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '8c7de168-2643-4235-8d38-be94ea42b7fe' User entered 'No (N)'	System	13 Dec 2020 16:05:20
	System	13 Dec 2020 16:05:20

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Have you been exposed to someone with 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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-12-13T10:05:15', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '8c7de168-2643-4235-8d38-be94ea42b7fe' User entered 'No (N)'	System	13 Dec 2020 16:05:20
	System	13 Dec 2020 16:05:20

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-12-13T10:05:18', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '8c7de168-2643-4235-8d38-be94ea42b7fe' User entered '13 Dec 2020 10:05:18'	System	13 Dec 2020 16:05:20
	System	13 Dec 2020 16:05:20

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-12-19T05:21:23', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '8e34763e-77ed-4c24-8d76-3a5261f535e9' User entered 'No (N)'	System	19 Dec 2020 11:21:32
	System	19 Dec 2020 11:21:32

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Have you been exposed to someone with 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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-12-19T05:21:26', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '8e34763e-77ed-4c24-8d76-3a5261f535e9' User entered 'No (N)'	System	19 Dec 2020 11:21:32
	System	19 Dec 2020 11:21:32

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-12-19T05:21:30', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '8e34763e-77ed-4c24-8d76-3a5261f535e9' User entered '19 Dec 2020 05:21:30'	System	19 Dec 2020 11:21:32
	System	19 Dec 2020 11:21:32

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-12-28T12:00:52', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '2409767e-3c09-4299-ac8a-258d7c73fbb7' User entered 'No (N)'	System	28 Dec 2020 18:01:20
	System	28 Dec 2020 18:01:20

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Have you been exposed to someone with 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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-12-28T12:00:57', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '2409767e-3c09-4299-ac8a-258d7c73fbb7'	System	28 Dec 2020 18:01:20
User entered 'No (N)'	System	28 Dec 2020 18:01:20

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2020-12-28T12:01:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '2409767e-3c09-4299-ac8a-258d7c73fbb7' User entered '28 Dec 2020 12:01:00'	System	28 Dec 2020 18:01:20
	System	28 Dec 2020 18:01:20

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-01-02T00:01:47', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '1b added7b1-7eca-4d9a-a1ed-824565f49867' User entered 'No (N)'	System	02 Jan 2021 06:02:00
	System	02 Jan 2021 06:02:00

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Have you been exposed to someone with 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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-01-02T00:01:53', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '1b added 7b1-7eca-4d9a-a1ed-824565f49867'	System	02 Jan 2021 06:02:00
User entered 'No (N)'	System	02 Jan 2021 06:02:00

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-01-02T00:01:56', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '1b added 7b1-7eca-4d9a-a1ed-824565f49867' User entered '02 Jan 2021 00:01:56'	System	02 Jan 2021 06:02:00
	System	02 Jan 2021 06:02:00

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-01-09T13:15:29', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '07a95c1f-f489-4a26-854f-b0e7bba94fdb' User entered 'No (N)'	System	09 Jan 2021 19:15:38

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Have you been exposed to someone with 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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-01-09T13:15:31', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '07a95c1f-f489-4a26-854f-b0e7bba94fdb' User entered 'No (N)'	System	09 Jan 2021 19:15:38

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-01-09T13:15:34', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '07a95c1f-f489-4a26-854f-b0e7bba94fdb' User entered '09 Jan 2021 13:15:34'	System	09 Jan 2021 19:15:38
	System	09 Jan 2021 19:15:38

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-01-17T22:42:40', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '9e340dec-f9fe-4c3b-9986-e514c88b4a2f' User entered 'No (N)'	System	18 Jan 2021 04:42:49
	System	18 Jan 2021 04:42:49

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Have you been exposed to someone with 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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-01-17T22:42:42', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '9e340dec-f9fe-4c3b-9986-e514c88b4a2f' User entered 'No (N)'	System	18 Jan 2021 04:42:49
	System	18 Jan 2021 04:42:49

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-01-17T22:42:45', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '9e340dec-f9fe-4c3b-9986-e514c88b4a2f' User entered '17 Jan 2021 22:42:45'	System	18 Jan 2021 04:42:49

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-01-23T00:02:52', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'f3e207ba-2f48-49d0-b8e8-e3f0bc8c366c' User entered 'No (N)'	System	23 Jan 2021 06:03:08
	System	23 Jan 2021 06:03:08

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Have you been exposed to someone with 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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-01-23T00:02:55', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'f3e207ba-2f48-49d0-b8e8-e3f0bc8c366c' User entered 'No (N)'	System	23 Jan 2021 06:03:08

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-01-23T00:02:59', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'f3e207ba-2f48-49d0-b8e8-e3f0bc8c366c' User entered '23 Jan 2021 00:02:59'	System	23 Jan 2021 06:03:08
	System	23 Jan 2021 06:03:08

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-01-30T18:52:26', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '4c4efa57-3b96-423d-9503-f7d792390700' User entered 'No (N)'	System	31 Jan 2021 00:52:35

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Have you been exposed to someone with 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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-01-30T18:52:29', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '4c4efa57-3b96-423d-9503-f7d792390700' User entered 'No (N)'	System	31 Jan 2021 00:52:35
	System	31 Jan 2021 00:52:35

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-01-30T18:52:32', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '4c4efa57-3b96-423d-9503-f7d792390700' User entered '30 Jan 2021 18:52:32'	System	31 Jan 2021 00:52:35
	System	31 Jan 2021 00:52:35

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-02-06T00:02:03', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '966be3cc-21f7-4b23-8b38-46b46e3f68d3' User entered 'No (N)'	System	06 Feb 2021 06:02:22
	System	06 Feb 2021 06:02:22

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Have you been exposed to someone with 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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-02-06T00:02:06', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '966be3cc-21f7-4b23-8b38-46b46e3f68d3' User entered 'No (N)'	System	06 Feb 2021 06:02:22
	System	06 Feb 2021 06:02:22

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-02-06T00:02:09', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '966be3cc-21f7-4b23-8b38-46b46e3f68d3' User entered '06 Feb 2021 00:02:09'	System	06 Feb 2021 06:02:22
	System	06 Feb 2021 06:02:22

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-02-16T17:59:16', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '06cbfb98-0875-459a-ab88-3ba35bf573fc' User entered 'No (N)'	System	16 Feb 2021 23:59:27
	System	16 Feb 2021 23:59:27

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Have you been exposed to someone with 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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-02-16T17:59:20', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '06cbfb98-0875-459a-ab88-3ba35bf573fc' User entered 'No (N)'	System	16 Feb 2021 23:59:27

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-02-16T17:59:23', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '06cbfb98-0875-459a-ab88-3ba35bf573fc' User entered '16 Feb 2021 17:59:23'	System	16 Feb 2021 23:59:27
	System	16 Feb 2021 23:59:27

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-02-20T17:07:06', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '73a05547-170f-43e7-ba15-1c13ec9e2020'	System	20 Feb 2021 23:10:45
User entered 'No (N)'	System	20 Feb 2021 23:10:45

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Have you been exposed to someone with 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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-02-20T17:07:08', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '73a05547-170f-43e7-ba15-1c13ec9e2020' User entered 'No (N)'	System	20 Feb 2021 23:10:45
	System	20 Feb 2021 23:10:45

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-02-20T17:07:11', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '73a05547-170f-43e7-ba15-1c13ec9e2020' User entered '20 Feb 2021 17:07:11'	System	20 Feb 2021 23:10:45
	System	20 Feb 2021 23:10:45

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-02-27T00:45:34', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'e4232f58-10c2-4205-b1c3-c0f6735742ec' User entered 'No (N)'	System	27 Feb 2021 05:45:53

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Have you been exposed to someone with 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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-02-27T00:45:46', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'e4232f58-10c2-4205-b1c3-c0f6735742ec' User entered 'No (N)'	System	27 Feb 2021 05:45:53

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-02-27T00:45:50', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'e4232f58-10c2-4205-b1c3-c0f6735742ec' User entered '27 Feb 2021 00:45:50'	System	27 Feb 2021 05:45:53
	System	27 Feb 2021 05:45:53

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-03-06T12:57:07-06:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '14c862e6-f296-469b-a809-54ea1906f2ac'	System	06 Mar 2021 18:57:19
User entered 'No (N)'	System	06 Mar 2021 18:57:19

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Have you been exposed to someone with 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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-03-06T12:57:11-06:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '14c862e6-f296-469b-a809-54ea1906f2ac'	System	06 Mar 2021 18:57:19
User entered 'No (N)'	System	06 Mar 2021 18:57:19

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-03-06T12:57:14-06:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '14c862e6-f296-469b-a809-54ea1906f2ac' User entered '06 Mar 2021 12:57:14'	System	06 Mar 2021 18:57:19
	System	06 Mar 2021 18:57:19

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-03-13T05:09:20-06:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '63a3e9f6-c451-4c88-a9ff-fd932d9d6186'	System	13 Mar 2021 11:09:47
User entered 'No (N)'	System	13 Mar 2021 11:09:47

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Have you been exposed to someone with 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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-03-13T05:09:28-06:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '63a3e9f6-c451-4c88-a9ff-fd932d9d6186'	System	13 Mar 2021 11:09:47
User entered 'No (N)'	System	13 Mar 2021 11:09:47

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-03-13T05:09:44-06:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '63a3e9f6-c451-4c88-a9ff-fd932d9d6186' User entered '13 Mar 2021 05:09:44'	System	13 Mar 2021 11:09:47
	System	13 Mar 2021 11:09:47

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-03-21T10:09:02-05:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'cf5b54c3-7206-43a0-afda-d21e16762d75'	System	21 Mar 2021 15:09:17
User entered 'No (N)'	System	21 Mar 2021 15:09:17

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Have you been exposed to someone with 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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-03-21T10:09:04-05:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'cf5b54c3-7206-43a0-afda-d21e16762d75'	System	21 Mar 2021 15:09:17
User entered 'No (N)'	System	21 Mar 2021 15:09:17

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-03-21T10:09:07-05:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'cf5b54c3-7206-43a0-afda-d21e16762d75'	System	21 Mar 2021 15:09:17
User entered '21 Mar 2021 10:09:07'	System	21 Mar 2021 15:09:17

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-03-28T08:58:36-05:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'a223d0b8-a7f5-43f9-a014-e58f38d9e682'	System	28 Mar 2021 13:58:44
User entered 'No (N)'	System	28 Mar 2021 13:58:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Have you been exposed to someone with 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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-03-28T08:58:39-05:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'a223d0b8-a7f5-43f9-a014-e58f38d9e682'	System	28 Mar 2021 13:58:44
User entered 'No (N)'	System	28 Mar 2021 13:58:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-03-28T08:58:42-05:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'a223d0b8-a7f5-43f9-a014-e58f38d9e682'	System	28 Mar 2021 13:58:44
User entered '28 Mar 2021 08:58:42'	System	28 Mar 2021 13:58:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-04-05T21:44:05-05:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '4e6a42bf-147f-4e69-ae40-e9967d10acc'	System	06 Apr 2021 02:44:20
User entered 'No (N)'	System	06 Apr 2021 02:44:20

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Have you been exposed to someone with 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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-04-05T21:44:08-05:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '4e6a42bf-147f-4e69-ae40-e9967d10acc'	System	06 Apr 2021 02:44:20
User entered 'No (N)'	System	06 Apr 2021 02:44:20

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-04-05T21:44:18-05:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '4e6a42bf-147f-4e69-ae40-e9967d10accc' User entered '05 Apr 2021 21:44:18'	System	06 Apr 2021 02:44:20
	System	06 Apr 2021 02:44:20

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-04-10T15:59:25-05:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'eaba2b39-259d-40c3-a460-c2c694792197'	System	10 Apr 2021 20:59:34
User entered 'No (N)'	System	10 Apr 2021 20:59:34

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Have you been exposed to someone with 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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-04-10T15:59:28-05:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'eaba2b39-259d-40c3-a460-c2c694792197'	System	10 Apr 2021 20:59:34
User entered 'No (N)'	System	10 Apr 2021 20:59:34

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-04-10T15:59:31-05:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'eaba2b39-259d-40c3-a460-c2c694792197'	System	10 Apr 2021 20:59:34
User entered '10 Apr 2021 15:59:31'	System	10 Apr 2021 20:59:34

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-04-17T00:10:01-05:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '63adc3fd-b521-4725-a804-f2ef30f2dc4e'	System	17 Apr 2021 05:10:11
User entered 'No (N)'	System	17 Apr 2021 05:10:11

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Have you been exposed to someone with 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 (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-04-17T00:10:04-05:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '63adc3fd-b521-4725-a804-f2ef30f2dc4e'	System	17 Apr 2021 05:10:11
User entered 'No (N)'	System	17 Apr 2021 05:10:11

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-04-17T00:10:07-05:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '63adc3fd-b521-4725-a804-f2ef30f2dc4e'	System	17 Apr 2021 05:10:11
User entered '17 Apr 2021 00:10:07'	System	17 Apr 2021 05:10:11

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[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 (3985CF8B-B8A8-4492-A933-84ED0580812B)', Time: '2021-04-27T11:47:33-05:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'c9cfe38d-3b5d-4419-ba27-52d4538c799e'	System	29 Apr 2021 04:29:12
User entered 'No (N)'	System	29 Apr 2021 04:29:12

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Have you been exposed to someone with 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 (3985CF8B-B8A8-4492-A933-84ED0580812B)', Time: '2021-04-27T11:47:35-05:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'c9cfe38d-3b5d-4419-ba27-52d4538c799e'	System	29 Apr 2021 04:29:12
User entered 'No (N)'	System	29 Apr 2021 04:29:12

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3985CF8B-B8A8-4492-A933-84ED0580812B)', Time: '2021-04-27T11:47:37-05:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'c9cfe38d-3b5d-4419-ba27-52d4538c799e' User entered '27 Apr 2021 11:47:37'	System	29 Apr 2021 04:29:12
	System	29 Apr 2021 04:29:12

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[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 (3985CF8B-B8A8-4492-A933-84ED0580812B)', Time: '2021-05-01T01:52:43-05:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'e0efea6d-5b07-4025-97f3-25e2a5331796'	System	01 May 2021 06:52:55
User entered 'No (N)'	System	01 May 2021 06:52:55

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

Have you been exposed to someone with 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 (3985CF8B-B8A8-4492-A933-84ED0580812B)', Time: '2021-05-01T01:52:47-05:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'e0efea6d-5b07-4025-97f3-25e2a5331796'	System	01 May 2021 06:52:55
User entered 'No (N)'	System	01 May 2021 06:52:55

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3985CF8B-B8A8-4492-A933-84ED0580812B)', Time: '2021-05-01T01:52:52-05:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: 'e0efea6d-5b07-4025-97f3-25e2a5331796'	System	01 May 2021 06:52:55
User entered '01 May 2021 01:52:52'	System	01 May 2021 06:52:55

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 11:24:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '26 Nov 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '30 Nov 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '03 Dec 2022 00:01'	System	20 Nov 2020 11:24:44

US3492281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:24:44
Amendment Manager: User entered '07 Dec 2022 23:59'	System	20 Nov 2020 11:24:44

US3492281

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:03:36

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 13:32:38
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 15:11:08
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' answered with 'done' (Site from DM).	Andrea Wendrow (b) (4)	01 Apr 2021 22:13:31
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 18:10:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-03-01T14:29:53-05:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '9fc1d869-dd75-447d-9356-ea7cf4f70cba'	System	01 Mar 2021 19:30:18
User entered 'Yes (Y)'	System	01 Mar 2021 19:30:18

US3492281

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:03:36

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:32:38
Comment added 'subject put yes but denied any use for medical condition when called for dermal filler alert use'.	Andrea Wendrow (b) (4)	01 Apr 2021 22:15:01
User entered 'No (N)' reason for change: New Information	Andrea Wendrow (b) (4)	01 Apr 2021 22:14:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-03-01T14:30:00-05:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '9fc1d869-dd75-447d-9356-ea7cf4f70cba'	System	01 Mar 2021 19:30:18
User entered 'Yes (Y)'	System	01 Mar 2021 19:30:18

US3492281

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:03:36

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:32:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C330D2-47C9-4DA1-823F-D02E288BBF57)', Time: '2021-03-01T14:30:03-05:00', User OID: 'PatientReportedOutcome (US3492281)', ODM File OID: '9fc1d869-dd75-447d-9356-ea7cf4f70cba'	System	01 Mar 2021 19:30:18
User entered '01 Mar 2021 14:30:03'	System	01 Mar 2021 19:30:18

US3492281

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	Ian Feather (b) (4)	21 Dec 2020 18:26:58

US3492281

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '21 Dec 2020'	Ian Feather (b) (4)	21 Dec 2020 18:26:58

US3492281

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Contact Made (CONTACT MADE)'	Ian Feather (b) (4)	21 Dec 2020 18:26:58

US3492281

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered empty.	Ian Feather (b) (4)	21 Dec 2020 18:26:58

US3492281

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	Ian Feather (b) (4)	21 Dec 2020 18:27:03

US3492281

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:39
User entered 'I'	System	21 Dec 2020 18:27:03

US3492281

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:43:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 16:56:52

US3492281

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:43:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 16:56:52

US3492281

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:43:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 16:56:52

US3492281

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:43:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 16:56:52

US3492281

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:43:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 16:56:59

US3492281

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:43:19
User entered 'I'	System	26 Jan 2021 16:56:59

US3492281

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:43:19
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	23 Feb 2021 18:18:25

US3492281

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:43:19
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered '23 Feb 2021'	Nia Moragne-O'Neal (b) (4)	23 Feb 2021 18:18:25

US3492281

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:43:19
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered 'Contact Made (CONTACT MADE)'	Nia Moragne-O'Neal (b) (4)	23 Feb 2021 18:18:25

US3492281

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:43:19
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered empty.	Nia Moragne-O'Neal (b) (4)	23 Feb 2021 18:18:25

US3492281

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:43:19
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	23 Feb 2021 18:18:31

US3492281

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:43:19
User entered 'I'	System	23 Feb 2021 18:18:31

US3492281

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:43:19
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered 'Yes (Y)'	Ian Feather (b) (4)	25 Mar 2021 13:27:31

US3492281

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:43:19
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered '25 Mar 2021'	Ian Feather (b) (4)	25 Mar 2021 13:27:31

US3492281

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:43:19
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered 'Contact Made (CONTACT MADE)'	Ian Feather (b) (4)	25 Mar 2021 13:27:31

US3492281

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:43:19
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered empty.	Ian Feather (b) (4)	25 Mar 2021 13:27:31

US3492281

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:43:19
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered 'Yes (Y)'	Ian Feather (b) (4)	25 Mar 2021 13:27:38

US3492281

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:43:19
User entered 'I'	System	25 Mar 2021 13:27:38

US3492281

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:44
	(b) (4)	
User entered 'Yes (Y)'	Diana Bahena (b) (4)	27 Apr 2021 16:49:50
	(b) (4)	

US3492281

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:44
	(b) (4)	
User entered '27 Apr 2021'	Diana Bahena (b) (4)	27 Apr 2021 16:49:50
	(b) (4)	

US3492281

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

[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 21:45:44
	(b) (4)	
User entered 'Clinic (Clinic)'	Diana Bahena (b) (4)	27 Apr 2021 16:49:50
	(b) (4)	

US3492281

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	27 Apr 2021 16:49:50

US3492281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:44
	(b) (4)	
User entered 'Yes (Y)'	Diana Bahena (b) (4)	27 Apr 2021 16:50:22
	(b) (4)	

US3492281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:44
	(b) (4)	
User entered '27 Apr 2021'	Diana Bahena (b) (4)	27 Apr 2021 16:50:22
	(b) (4)	

US3492281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:44
	(b) (4)	
User entered '11:42'	Diana Bahena (b) (4)	27 Apr 2021 16:50:22
	(b) (4)	

US3492281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
User entered '27 Apr 2021 11:42'	System	27 Apr 2021 16:50:22

US3492281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:44
	(b) (4)	
User entered '97.6' F	Diana Bahena (b) (4)	27 Apr 2021 16:50:22
	(b) (4)	

US3492281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:44
	(b) (4)	
User entered 'Other (Other)'	Diana Bahena (b) (4)	27 Apr 2021 16:50:22
	(b) (4)	

US3492281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:44
	(b) (4)	
User entered 'tympanic'	Diana Bahena (b) (4)	27 Apr 2021 16:50:22
	(b) (4)	

US3492281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:44
	(b) (4)	
User entered '83'	Diana Bahena (b) (4)	27 Apr 2021 16:50:22
	(b) (4)	

US3492281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	27 Apr 2021 16:50:22

US3492281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:44
	(b) (4)	
User entered '16'	Diana Bahena (b) (4)	27 Apr 2021 16:50:22
	(b) (4)	

US3492281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	27 Apr 2021 16:50:22

US3492281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:44
	(b) (4)	
User entered '111'	Diana Bahena (b) (4)	27 Apr 2021 16:50:22
	(b) (4)	

US3492281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Apr 2021 16:50:22

US3492281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:44
	(b) (4)	
User entered '76'	Diana Bahena (b) (4)	27 Apr 2021 16:50:22
	(b) (4)	

US3492281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Apr 2021 16:50:22

US3492281

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:44
	(b) (4)	
User entered 'Yes (Y)'	Diana Bahena (b) (4)	27 Apr 2021 16:50:30
	(b) (4)	

US3492281

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:44
	(b) (4)	
User entered '27 Apr 2021'	Diana Bahena (b) (4)	27 Apr 2021 16:50:30
	(b) (4)	

US3492281

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:44
	(b) (4)	
User entered 'Yes (Y)'	Diana Bahena (b) (4)	27 Apr 2021 16:50:57
	(b) (4)	

US3492281

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:44
	(b) (4)	
User entered '27 Apr 2021'	Diana Bahena (b) (4)	27 Apr 2021 16:50:57
	(b) (4)	

US3492281

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:44
	(b) (4)	
User entered '11:37'	Diana Bahena (b) (4)	27 Apr 2021 16:50:57
	(b) (4)	

US3492281

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
User entered '27 Apr 2021 11:37'	System	27 Apr 2021 16:50:57

US3492281

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:44
	(b) (4)	
User entered 'Yes (Y)'	Diana Bahena (b) (4)	27 Apr 2021 16:51:01
	(b) (4)	

US3492281

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 16:51:01

US3492281

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

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:30:39

US3492281

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

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '15 Jan 2021'	(b) (4) Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:30:39

US3492281

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

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Clinic (Clinic)'	Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:30:39

US3492281

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

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 19:30:39

US3492281

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

Form: Unblinding

Generated On: 10 Jun 2021 08:03:36

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '15 Jan 2021' reason for change: Data Entry Error	(b) (4)	21 Jan 2021 19:53:52
User entered '24 Dec 2020' reason for change: Data Entry Error	Lorna Sanchez McCann (b) (4)	15 Jan 2021 22:02:08
User entered '15 Jan 2021'	Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:30:52

US3492281

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

Form: Unblinding

Generated On: 10 Jun 2021 08:03:36

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:11:52

US3492281

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

Form: Unblinding

Generated On: 10 Jun 2021 08:03:36

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:30:52

US3492281

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

Form: Unblinding

Generated On: 10 Jun 2021 08:03:36

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
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 20:11:52

US3492281

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

Form: Unblinding

Generated On: 10 Jun 2021 08:03:36

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '15 Jan 2021'	(b) (4) Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:30:52

US3492281

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

Form: Unblinding

Generated On: 10 Jun 2021 08:03:36

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Placebo (Placebo)'	Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:30:52

US3492281

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

Form: Unblinding

Generated On: 10 Jun 2021 08:03:36

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 15:45:40
User entered 'Placebo (Placebo)'	Lorna Sanchez McCann	15 Jan 2021 19:30:52
	(b) (4)	

US3492281

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

Form: Unblinding

Generated On: 10 Jun 2021 08:03:36

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 15:45:40
User entered 'Placebo (Placebo)'	Lorna Sanchez McCann	15 Jan 2021 19:30:52
	(b) (4)	

US3492281

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

Form: Unblinding

Generated On: 10 Jun 2021 08:03:36

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:30:52

US3492281

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

Form: Unblinding

Generated On: 10 Jun 2021 08:03:36

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered '1'	System	15 Jan 2021 19:30:52

US3492281

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

Form: Unblinding

Generated On: 10 Jun 2021 08:03:36

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'I'	System	15 Jan 2021 19:30:52

US3492281

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered missing code ND - Not Done.	(b) (4) Lorna Sanchez McCann	15 Jan 2021 19:35:48
	(b) (4)	

US3492281

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered missing code ND - Not Done.	(b) (4) Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:35:48

US3492281

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:36

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered empty.	System	15 Jan 2021 19:35:48
DataPoint set to visible.	System	15 Jan 2021 19:30:52

US3492281

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered missing code ND - Not Done.	(b) (4) Lorna Sanchez McCann	15 Jan 2021 19:35:48
	(b) (4)	

US3492281

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered missing code ND - Not Done.	(b) (4) Lorna Sanchez McCann	15 Jan 2021 19:35:48
	(b) (4)	

US3492281

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:36

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered empty.	System	15 Jan 2021 19:35:48
DataPoint set to visible.	System	15 Jan 2021 19:30:52

US3492281

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User accepted default value 'Pre-Dose (PREDOSE)'	Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:35:48

US3492281

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:35:48

US3492281

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '15 Jan 2021'	Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:35:48

US3492281

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '13:08'	Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:35:48

US3492281

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered '15 Jan 2021 13:08'	System	15 Jan 2021 19:35:48

US3492281

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '36.8' C	Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:35:48

US3492281

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Other (Other)'	Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:35:48

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'tympanic'	(b) (4) Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:35:48

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '73'	Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:35:48

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'bpm'	System	15 Jan 2021 19:35:48

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '16'	Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:35:48

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'breaths/min'	System	15 Jan 2021 19:35:48

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '125'	Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:35:48

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'mmHg'	System	15 Jan 2021 19:35:48

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '76'	Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:35:48

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'mmHg'	System	15 Jan 2021 19:35:48

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered missing code ND - Not Done.	(b) (4) Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:35:48

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered missing code ND - Not Done.	(b) (4) Lorna Sanchez McCann	15 Jan 2021 19:35:48
	(b) (4)	

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:36

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered empty.	System	15 Jan 2021 19:35:48
DataPoint set to visible.	System	15 Jan 2021 19:30:52

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User accepted default value 'Post-Dose (POSTDOSE)'	Marla Schwarber (b) (4) (b) (4)	15 Jan 2021 20:08:43

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	Marla Schwarber (b) (4)	15 Jan 2021 20:08:43

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '15 Jan 2021'	(b) (4) Marla Schwarber (b) (4)	15 Jan 2021 20:08:43

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '14:00'	Marla Schwarber (b) (4)	15 Jan 2021 20:08:43

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered '15 Jan 2021 14:00'	System	15 Jan 2021 20:08:43

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '36.7' C	Marla Schwarber (b) (4)	15 Jan 2021 20:08:43

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Other (Other)'	Marla Schwarber (b) (4)	15 Jan 2021 20:08:43

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Tympanic'	Marla Schwarber (b) (4)	15 Jan 2021 20:08:43

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '86'	Marla Schwarber (b) (4)	15 Jan 2021 20:08:43

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'bpm'	System	15 Jan 2021 20:08:43

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '16'	Marla Schwarber (b) (4)	15 Jan 2021 20:08:43

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'breaths/min'	System	15 Jan 2021 20:08:43

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '117'	Marla Schwarber (b) (4)	15 Jan 2021 20:08:43

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'mmHg'	System	15 Jan 2021 20:08:43

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '77'	Marla Schwarber (b) (4)	15 Jan 2021 20:08:43

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'mmHg'	System	15 Jan 2021 20:08:43

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:31:00

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '15 Jan 2021'	Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:31:00

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	Marla Schwarber (b) (4)	15 Jan 2021 19:57:44

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered empty.	Marla Schwarber (b) (4)	15 Jan 2021 19:57:44

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered empty.	Marla Schwarber (b) (4)	15 Jan 2021 19:57:44

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'mRNA-1273'	System	15 Jan 2021 19:57:44
DataPoint set to visible.	System	15 Jan 2021 19:30:52

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '15 Jan 2021'	Marla Schwarber (b) (4)	15 Jan 2021 19:57:44

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '13:42'	(b) (4) Marla Schwarber (b) (4)	15 Jan 2021 19:57:44

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered '15 Jan 2021 13:42'	System	15 Jan 2021 19:57:44

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Left Arm (LEFT ARM)'	Marla Schwarber (b) (4)	15 Jan 2021 19:57:44

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'ONCE'	System	15 Jan 2021 19:57:44

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'INTRAMUSCULAR'	System	15 Jan 2021 19:57:44

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:33:41

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '15 Jan 2021'	(b) (4) Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:33:41

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:36

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '13:25'	Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:33:41

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered '15 Jan 2021 13:25'	System	15 Jan 2021 19:33:41

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:03:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:33:51

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:03:36

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '15 Jan 2021'	Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:33:51

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:03:36

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '13:32'	Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:33:51

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:03:36

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered '15 Jan 2021 13:32'	System	15 Jan 2021 19:33:51

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	15 Jan 2021 19:33:54

US3492281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'I'	System	15 Jan 2021 19:33:54

US3492281

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	22 Jan 2021 20:44:42

US3492281

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '22 Jan 2021'	Nia Moragne-O'Neal (b) (4)	22 Jan 2021 20:44:42

US3492281

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Contact Made (CONTACT MADE)'	Nia Moragne-O'Neal (b) (4)	22 Jan 2021 20:44:42

US3492281

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered empty.	Nia Moragne-O'Neal (b) (4)	22 Jan 2021 20:44:42

US3492281

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	22 Jan 2021 20:44:45

US3492281

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'I'	System	22 Jan 2021 20:44:45

US3492281

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered '1'	System	22 Jan 2021 20:44:45
DataPoint set to visible.	System	22 Jan 2021 20:44:45

US3492281

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:03:45

US3492281

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '9 Feb 2021'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:03:45

US3492281

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Clinic (Clinic)'	Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:03:45

US3492281

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'OLD29'	System	09 Feb 2021 15:03:45

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User accepted default value 'Pre-Dose (PREDOSE)'	Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:37:27

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:37:27

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '9 Feb 2021'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:37:27

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '09:05'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:37:27

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered '9 Feb 2021 09:05'	System	09 Feb 2021 15:37:27

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '97.9' F	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:37:27

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Other (Other)'	Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:37:27

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'tympanic'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:37:27

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '94'	Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:37:27

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'bpm'	System	09 Feb 2021 15:37:27

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '16'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:37:27

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'breaths/min'	System	09 Feb 2021 15:37:27

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '115'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:37:27

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'mmHg'	System	09 Feb 2021 15:37:27

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '75'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:37:27

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'mmHg'	System	09 Feb 2021 15:37:27

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	09 Feb 2021 15:52:07

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:52:07

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:52:07

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '09:48'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:52:07

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered '9 Feb 2021 09:48'	System	09 Feb 2021 15:52:07

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
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)	10 Feb 2021 13:17:52
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)	09 Feb 2021 20:47:57
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	09 Feb 2021 15:52:07
User entered '35.9' C	(b) (4), (b) (6)	09 Feb 2021 15:52:07

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:52:07

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Tympanic'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:52:07

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '82'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:52:07

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'bpm'	System	09 Feb 2021 15:52:07

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '18'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:52:07

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'breaths/min'	System	09 Feb 2021 15:52:07

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '116'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:52:07

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'mmHg'	System	09 Feb 2021 15:52:07

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '73'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:52:07

US3492281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'mmHg'	System	09 Feb 2021 15:52:07

US3492281

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:03:57

US3492281

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '9 Feb 2021'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:03:57

US3492281

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:53:10

US3492281

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:53:10

US3492281

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:53:10

US3492281

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'mRNA-1273'	System	09 Feb 2021 15:53:10
DataPoint set to visible.	System	22 Jan 2021 20:44:45

US3492281

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:53:10

US3492281

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '09:45'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:53:10

US3492281

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered '9 Feb 2021 09:45'	System	09 Feb 2021 15:53:10

US3492281

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:53:10

US3492281

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'ONCE'	System	09 Feb 2021 15:53:10

US3492281

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:36

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'INTRAMUSCULAR'	System	09 Feb 2021 15:53:10

US3492281

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:03:50

US3492281

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'I'	System	09 Feb 2021 15:03:50

US3492281

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:04:03

US3492281

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered '17 Feb 2021'	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:04:03

US3492281

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered 'Contact Made (CONTACT MADE)'	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:04:03

US3492281

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered empty.	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:04:03

US3492281

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:04:06

US3492281

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'I'	System	17 Feb 2021 15:04:06

US3492281

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	09 Mar 2021 16:21:40

US3492281

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
User entered '9 Mar 2021'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Mar 2021 16:21:40

US3492281

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
User entered 'Clinic (Clinic)'	Lorna Sanchez McCann (b) (4)	09 Mar 2021 16:21:40

US3492281

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'OLD57'	System	09 Mar 2021 16:21:40

US3492281

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	09 Mar 2021 16:22:44

US3492281

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered '9 Mar 2021'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Mar 2021 16:22:44

US3492281

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered '09:02'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Mar 2021 16:22:44

US3492281

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered '9 Mar 2021 09:02'	System	09 Mar 2021 16:22:44

US3492281

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered '98.2' F	Lorna Sanchez McCann (b) (4)	09 Mar 2021 16:22:44

US3492281

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered 'Other (Other)'	Lorna Sanchez McCann (b) (4)	09 Mar 2021 16:22:44

US3492281

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered 'tympanic'	Lorna Sanchez McCann (b) (4)	09 Mar 2021 16:22:44

US3492281

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered '99'	Lorna Sanchez McCann (b) (4)	09 Mar 2021 16:22:44

US3492281

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'bpm'	System	09 Mar 2021 16:22:44

US3492281

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered '14'	Lorna Sanchez McCann (b) (4)	09 Mar 2021 16:22:44

US3492281

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'breaths/min'	System	09 Mar 2021 16:22:44

US3492281

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered '132'	Lorna Sanchez McCann (b) (4)	09 Mar 2021 16:22:44

US3492281

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'mmHg'	System	09 Mar 2021 16:22:44

US3492281

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered '85'	Lorna Sanchez McCann (b) (4)	09 Mar 2021 16:22:44

US3492281

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered 'mmHg'	System	09 Mar 2021 16:22:44

US3492281

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54

US3492281

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:36

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54

US3492281

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	09 Mar 2021 16:22:50

US3492281

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
User entered '9 Mar 2021'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Mar 2021 16:22:50

US3492281

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	09 Mar 2021 16:23:03

US3492281

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
User entered '9 Mar 2021'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Mar 2021 16:23:03

US3492281

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:36

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
User entered '09:05'	Lorna Sanchez McCann (b) (4)	09 Mar 2021 16:23:03

US3492281

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:13:54
User entered '9 Mar 2021 09:05'	System	09 Mar 2021 16:23:03

US3492281

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:03:36

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:30
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	29 Oct 2020 21:51:26

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 21:53:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 21:53:44
Data point term sent to Coder	System	29 Oct 2020 21:53:15
User entered 'sore throat'	Andrea Wendrow (b) (4)	29 Oct 2020 21:52:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	29 Oct 2020 21:52:51

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 21:52:51

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	29 Oct 2020 21:52:51

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '3 Oct 2020'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	29 Oct 2020 21:52:51

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	Andrea Wendrow (b) (4)	29 Oct 2020 21:52:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
User entered empty.	System	29 Oct 2020 21:52:51

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	29 Oct 2020 21:52:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '4 Oct 2020'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 21:52:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	(b) (4) Andrea Wendrow (b) (4) (b) (4)	29 Oct 2020 21:52:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
User entered empty.	System	29 Oct 2020 21:52:51

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Grade 1/Mild (Grade 1/Mild)'	Andrea Wendrow (b) (4)	29 Oct 2020 21:52:51

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 21:52:51

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '0'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	29 Oct 2020 21:52:51

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 21:52:51

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '0'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	29 Oct 2020 21:52:51

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	Andrea Wendrow (b) (4)	29 Oct 2020 21:52:51

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	Andrea Wendrow (b) (4)	29 Oct 2020 21:52:51

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	Andrea Wendrow (b) (4)	29 Oct 2020 21:52:51

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	Andrea Wendrow (b) (4)	29 Oct 2020 21:52:51

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '0'	Andrea Wendrow (b) (4)	29 Oct 2020 21:52:51

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '0'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	29 Oct 2020 21:52:51

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '0'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	29 Oct 2020 21:52:51

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4)	29 Oct 2020 21:52:51

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4)	29 Oct 2020 21:52:51

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'None (NONE)'	Andrea Wendrow (b) (4)	29 Oct 2020 21:52:51

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'I'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 21:52:51

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '0'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	29 Oct 2020 21:52:51

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '0'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	29 Oct 2020 21:52:51

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	29 Oct 2020 21:52:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	Andrea Wendrow (b) (4)	29 Oct 2020 21:52:51

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	Andrea Wendrow (b) (4)	29 Oct 2020 21:52:51

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
User entered '0'	System	29 Oct 2020 21:52:51

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07
User entered '0'	System	29 Oct 2020 21:52:51

US3492281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:36

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:07

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Rhinorrhea - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 22:18:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 22:18:53
Data point term sent to Coder	System	29 Oct 2020 22:03:26
User entered 'Rhinorrhea'	Andrea Wendrow (b) (4)	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '3 Oct 2020'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	Andrea Wendrow (b) (4)	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
User entered empty.	System	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '4 Oct 2020'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	Andrea Wendrow (b) (4)	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
User entered empty.	System	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Grade 1/Mild (Grade 1/Mild)'	Andrea Wendrow (b) (4)	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '0'	Andrea Wendrow (b) (4)	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	Andrea Wendrow (b) (4)	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	Andrea Wendrow (b) (4)	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '0'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '0'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4)	29 Oct 2020 22:03:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4)	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Oct 2020 22:03:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Oct 2020 22:03:17
User entered 'None (NONE)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	29 Oct 2020 22:03:17
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Oct 2020 22:03:01
User entered empty.	System	29 Oct 2020 22:03:01
	Andrea Wendrow (b) (4)	29 Oct 2020 22:03:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'l'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '0'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '0'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Oct 2020 22:03:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	System	29 Oct 2020 22:03:17
Data Entry Error	Andrea Wendrow (b) (4)	29 Oct 2020 22:03:17
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	29 Oct 2020 22:03:01
	Andrea Wendrow (b) (4)	29 Oct 2020 22:03:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	Andrea Wendrow (b) (4)	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	(b) (4)	
	Andrea Wendrow (b) (4)	29 Oct 2020 22:03:01
	(b) (4)	

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
User entered '0'	System	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12
User entered '0'	System	29 Oct 2020 22:03:01

US3492281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:36

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:12

US3492281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:36

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:18
User entered 'USA-US101-2021-mRNA-1273-P301000007'	System	10 Feb 2021 14:19:15
User entered 'New'	(b) (4), (b) (6)	10 Feb 2021 14:19:15

US3492281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:36

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Tendon rupture, LLT: Tendon rupture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 11:56:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 11:56:48
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:31:54
Data point term sent to Coder	System	09 Feb 2021 15:22:02
User entered 'torn tendon in left wrist'	Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:21:55

US3492281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann	09 Feb 2021 15:21:55
	(b) (4)	

US3492281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'No (N)'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:21:55

US3492281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'No (N)'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:21:55

US3492281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:36

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '21 Dec 2020'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:21:55

US3492281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:36

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	(b) (4) Lorna Sanchez McCann	09 Feb 2021 15:21:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 15:21:55

US3492281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:43
	(b) (4)	
User entered 'Yes (Y)' reason for change: Per Query Resolution	Diana Bahena (b) (4)	19 Apr 2021 21:31:39
DataPoint Un-verified.	(b) (4)	
	Michelle Agnoli (b) (4)	15 Apr 2021 19:31:57
	(b) (4)	
Signature has been broken.	Michelle Agnoli (b) (4)	15 Apr 2021 19:31:57
	(b) (4)	
User entered 'No (N)' reason for change: Per Query Resolution	Michelle Agnoli (b) (4)	15 Apr 2021 19:31:57
	(b) (4)	
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 01:36:47
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.'	Michelle Agnoli (b) (4)	11 Mar 2021 20:24:29
answered with 'This AE is still ongoing as of 23FEB2021, day 149 safety call.' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 10:58:30
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'Yes (Y)'	Lorna Sanchez McCann	09 Feb 2021 15:21:55
	(b) (4)	

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	27 Apr 2021 23:48:45 26 Apr 2021 16:34:43
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System System	19 Apr 2021 21:32:39 19 Apr 2021 21:32:39
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	19 Apr 2021 21:31:39
User entered empty; reason for change Per Query Resolution	Diana Bahena (b) (4) (b) (4)	19 Apr 2021 21:31:39
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System System	15 Apr 2021 19:35:28 15 Apr 2021 19:35:28
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System). DataPoint Un-verified.	System Michelle Agnoli (b) (4) (b) (4)	15 Apr 2021 19:35:28 15 Apr 2021 19:35:28
Signature has been broken.	Michelle Agnoli (b) (4) (b) (4)	15 Apr 2021 19:35:28
User entered '15 Apr 2021' reason for change: Per Query Resolution	Michelle Agnoli (b) (4) (b) (4)	15 Apr 2021 19:35:28
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	15 Apr 2021 19:31:57
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). DataPoint Verified.	System (b) (4), (b) (6)	15 Apr 2021 19:31:57 04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:31:54

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If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:21:55

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:21:55

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 23:48:55
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 15:42:04
User entered empty.	System	09 Feb 2021 15:21:55

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Severity

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
Query 'PV Query: Since the subject was hospitalized for the event of torn tendon in left wrist, appropriate CTCAE grade should be grade 3 instead of grade 1/grade 2. Please update the event severity as such. If the severity is to remain grade 1/grade 2, please clarify/explain.' canceled (Site from Safety). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:53:39
	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User opened query 'PV Query: Since the subject was hospitalized for the event of torn tendon in left wrist, appropriate CTCAE grade should be grade 3 instead of grade 1/grade 2. Please update the event severity as such. If the severity is to remain grade 1/grade 2, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 15:03:23
Signature has been broken.	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:01:09
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: New Information	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:01:09
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:31:54
User entered 'Grade 3/Severe (Grade 3/Severe)'	Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:21:55

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	(b) (4)	09 Feb 2021 15:22:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:22:18
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 15:22:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 15:22:04
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	09 Feb 2021 15:22:04
User entered 'No (N)' reason for change: Data Entry Error	Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:22:04
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 15:21:55
User entered empty.	Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:21:55

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '0'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:21:55

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Form: Adverse Events (3)

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '0'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:21:55

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'I'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:21:55

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '21 Dec 2020'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:21:55

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Form: Adverse Events (3)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '22 Dec 2020'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:21:55

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Form: Adverse Events (3)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'No (N)'	(b) (4) Lorna Sanchez McCann	09 Feb 2021 15:21:55
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	(b) (4) Lorna Sanchez McCann	09 Feb 2021 15:21:55
	(b) (4)	

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '0'	(b) (4) Lorna Sanchez McCann	09 Feb 2021 15:21:55
	(b) (4)	

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '0'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:21:55

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '0'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:21:55

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Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Not Related (NOT RELATED)'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:21:55

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Not Related (NOT RELATED)'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:21:55

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Folder: Adverse Events

Form: Adverse Events (3)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
User closed query 'PV Query: As the subject received both doses of placebo prior to the onset of the event, please consider updating the action taken to not applicable. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:40:22
Query 'PV Query: As the subject received both doses of placebo prior to the onset of the event, please consider updating the action taken to not applicable. ' answered with 'Updated to not applicable per query resolution.' (Site from Safety).	Michelle Agnoli (b) (4) (b) (4)	11 Mar 2021 20:27:25
DataPoint Un-verified.	Michelle Agnoli (b) (4) (b) (4)	11 Mar 2021 20:25:11
Signature has been broken.	Michelle Agnoli (b) (4) (b) (4)	11 Mar 2021 20:25:11
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Michelle Agnoli (b) (4) (b) (4)	11 Mar 2021 20:25:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User opened query 'PV Query: As the subject received both doses of placebo prior to the onset of the event, please consider updating the action taken to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 15:41:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:31:54
User entered 'None (NONE)'	Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:21:55

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '0'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:21:55

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'I'	(b) (4) Lorna Sanchez McCann	09 Feb 2021 15:21:55
	(b) (4)	

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Form: Adverse Events (3)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
	(b) (4)	
DataPoint Un-verified.	Michelle Agnoli (b) (4)	19 Mar 2021 20:12:45
	(b) (4)	
Signature has been broken.	Michelle Agnoli (b) (4)	19 Mar 2021 20:12:45
	(b) (4)	
User entered '1' reason for change: Per Query Resolution	Michelle Agnoli (b) (4)	19 Mar 2021 20:12:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered '0'	Lorna Sanchez McCann	09 Feb 2021 15:21:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:36

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:43
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Per Query Resolution	Diana Bahena (b) (4)	19 Apr 2021 21:32:39
	(b) (4)	
User closed query 'PV Query: If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. Please provide the final event outcome, when available. Please leave query open until information is received. ' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 18:57:50
DataPoint Un-verified.	Michelle Agnoli (b) (4)	15 Apr 2021 19:31:57
	(b) (4)	
Signature has been broken.	Michelle Agnoli (b) (4)	15 Apr 2021 19:31:57
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution	Michelle Agnoli (b) (4)	15 Apr 2021 19:31:57
	(b) (4)	
Query 'PV Query: If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. Please provide the final event outcome, when available. Please leave query open until information is received. ' answered with 'patient stabilized with ongoing symptoms and medication' (Site from Safety).	Michelle Agnoli (b) (4)	15 Apr 2021 19:29:45
	(b) (4)	
User opened query 'PV Query: If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. Please provide the final event outcome, when available. Please leave query open until information is received. ' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 17:18:59

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[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. Please provide the final event outcome, when available.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 17:19:55
Query 'PV Query: If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. Please provide the final event outcome, when available.' answered with 'This patient is still recovering from condition ' (Site from Safety).	Michelle Agnoli (b) (4)	19 Mar 2021 20:05:21
User opened query 'PV Query: If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. Please provide the final event outcome, when available.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 13:33:22
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 13:40:35
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved' answered with 'As of Safety call, day 149, 23Feb2021, outcome is still recovering/resolving' (Site from Safety).	Michelle Agnoli (b) (4)	11 Mar 2021 20:28:53
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 15:44:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:21:55

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:21:55

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:43
	(b) (4)	
User entered 'PPT STRUCK BY MOTOR VEHICLE AND RECEIVING PHYSICAL THERAPY-RECOVERED/RESOLVED PER PV REQUEST.	Diana Bahena (b) (4)	22 Apr 2021 16:29:33
	(b) (4)	
19APR2021- Ppt reports not completely healed but improving.' reason for change: Per Query Resolution DataPoint Un-verified.	Michelle Agnoli (b) (4)	15 Apr 2021 19:31:57
	(b) (4)	
Signature has been broken.	Michelle Agnoli (b) (4)	15 Apr 2021 19:31:57
	(b) (4)	
User entered 'PPT STRUCK BY MOTOR VEHICLE AND RECEIVING PHYSICAL THERAPY-recovered/resolved per PV request' reason for change: Per Query Resolution	Michelle Agnoli (b) (4)	15 Apr 2021 19:31:57
	(b) (4)	
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 13:41:27
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 13:40:45
User closed query 'Per DM CLR: Narrative = RECEIVING PHYSICAL THERAPY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 01:37:59
Query 'Per DM CLR: Narrative = RECEIVING PHYSICAL THERAPY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' answered with 'Started 04Jan2021 and is continuing' (Site from DM).	Michelle Agnoli (b) (4)	11 Mar 2021 20:40:54
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'not applicable' (Site from Safety).	Michelle Agnoli (b) (4)	11 Mar 2021 20:30:57
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' answered with 'COVID-19 testing not done.' (Site from Safety).	Michelle Agnoli (b) (4)	11 Mar 2021 20:30:00
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User opened query 'Per DM CLR: Narrative = RECEIVING PHYSICAL THERAPY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 10:58:18
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved' canceled (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 15:02:43
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 15:42:44
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 15:42:23
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 15:41:34

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'ppt struck by motor vehicle and receiving physical therapy'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:21:55

US3492281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Feb 2021 15:22:18
User entered '0'	System	09 Feb 2021 15:22:04

US3492281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Feb 2021 15:21:55

US3492281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:36

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Feb 2021 15:21:55

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 05:27:56
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'recorded as protocol deviation' (Site from DM).	Michelle Agnoli (b) (4) (b) (4)	19 Mar 2021 20:35:09
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 16:20:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Nasal congestion, LLT: Nasal congestion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 15:05:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 15:05:00
Data point term sent to Coder	System	17 Feb 2021 15:04:17
User entered 'nasal CONGESTION' reason for change: Data Entry Error	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:38
Data point term sent to Coder	System	17 Feb 2021 15:03:15
User entered 'Congestion'	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:18
User entered 'No (N)'	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:18
User entered 'No (N)'	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:18
User entered 'No (N)'	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:18
User entered '11 Feb 2021'	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:18
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	17 Feb 2021 15:03:26
User entered empty; reason for change Data Entry Error	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:26
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	17 Feb 2021 15:03:06
User entered '12:00'	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User entered empty.	System	17 Feb 2021 15:03:26
User entered '11 Feb 2021 12:00'	System	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:18
User entered 'No (N)'	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:18
User entered '15 Feb 2021'	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:18
User entered empty.	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User entered empty.	System	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:18
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:18
User entered 'No (N)'	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:18
User entered '0'	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:18
User entered '0'	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:18
User entered '0'	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:18
User entered empty.	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:18
User entered empty.	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:18
User entered empty.	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:18
User entered empty.	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:18
User entered '0'	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:18
User entered '0'	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:18
User entered '0'	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:18
User entered 'Not Related (NOT RELATED)'	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:18
User entered 'Not Related (NOT RELATED)'	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:18
User entered 'None (NONE)'	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:18
User entered 'I'	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:18
User entered '0'	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:18
User entered '0'	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:18
User entered empty.	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:18
User entered empty.	Nia Moragne-O'Neal (b) (4)	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User entered '0'	System	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17
User entered '0'	System	17 Feb 2021 15:03:06

US3492281

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:36

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:05:17

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:03:36

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:30
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Yes (Y)'	Diana Bahena (b) (4)	01 Oct 2020 15:00:35

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Oct 2020 15:02:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 15:02:46
Data point term sent to Coder	System	01 Oct 2020 15:02:12
User entered 'Finasteride'	Diana Bahena (b) (4) (b) (4)	01 Oct 2020 15:01:13

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'No (N)'	Diana Bahena (b) (4)	01 Oct 2020 15:01:13
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User closed query 'Per CDM re-query: Response states 'updated' however there is no corresponding record present on MH page. Please review and update as appropriate or clarify what was updated.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 07:23:04
Query 'Per CDM re-query: Response states 'updated' however there is no corresponding record present on MH page. Please review and update as appropriate or clarify what was updated.' answered with 'MH updated' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	09 Dec 2020 23:44:00
User opened query 'Per CDM re-query: Response states 'updated' however there is no corresponding record present on MH page. Please review and update as appropriate or clarify what was updated.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 15:06:26
User closed query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 15:06:26
Query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' answered with 'updated' (Site from DM).	Lorna Sanchez McCann (b) (4)	02 Dec 2020 20:47:04
User opened query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 06:54:57
User entered 'Hair loss'	Diana Bahena (b) (4) (b) (4)	01 Oct 2020 15:01:13

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
	(b) (4)	
Signature has been broken.	Michelle Agnoli (b) (4)	11 Mar 2021 20:50:26
	(b) (4)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'l'	Diana Bahena (b) (4)	01 Oct 2020 15:01:13
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'mg (mg)'	Diana Bahena (b) (4)	01 Oct 2020 15:01:13
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered empty.	Diana Bahena (b) (4)	01 Oct 2020 15:01:13
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'once daily (QD)'	Diana Bahena (b) (4)	01 Oct 2020 15:01:13
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered empty.	Diana Bahena (b) (4)	01 Oct 2020 15:01:13
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'Oral (ORAL)'	Diana Bahena (b) (4)	01 Oct 2020 15:01:13
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered empty.	Diana Bahena (b) (4)	01 Oct 2020 15:01:13
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:36

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'un UNK 2017'	Diana Bahena (b) (4)	01 Oct 2020 15:01:13
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered '0'	Diana Bahena (b) (4)	01 Oct 2020 15:01:13
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'Yes (Y)'	Diana Bahena (b) (4)	01 Oct 2020 15:01:13
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered empty.	Diana Bahena (b) (4)	01 Oct 2020 15:01:13
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'No (N)'	Diana Bahena (b) (4)	01 Oct 2020 15:01:13
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:01:13

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:01:13

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 15:01:13

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS, PRODUCT: EMTRICITABINE;TENOFOVIR DISOPROXIL FUMARATE, PRODUCTSYNONYM: TRUVADA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Oct 2020 09:00:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 09:00:45
Data point term sent to Coder	System	01 Oct 2020 15:03:13
User entered 'Tenofovir disoproxil fumarate and emtricitabine (Truvada)'	Diana Bahena (b) (4) (b) (4)	01 Oct 2020 15:02:56

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User closed query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:06:40
Query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	Lorna Sanchez McCann (b) (4)	02 Dec 2020 18:32:12
User entered 'Yes (Y)' reason for change: Per Query Resolution	Lorna Sanchez McCann (b) (4)	02 Dec 2020 18:31:54
User opened query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 06:55:19
User entered 'No (N)'	Diana Bahena (b) (4) (b) (4)	01 Oct 2020 15:02:56

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'PrEP'	Diana Bahena (b) (4)	01 Oct 2020 15:02:56
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug (e.g 200/300 or 100/150). Update the Dose and Dose Unit fields as appropriate. Otherwise provide clarification ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:18:20
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug (e.g 200/300 or 100/150). Update the Dose and Dose Unit fields as appropriate. Otherwise provide clarification ' answered with 'corrected' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	22 Jan 2021 16:14:44
User entered '300/200' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	22 Jan 2021 16:14:35
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug (e.g 200/300 or 100/150). Update the Dose and Dose Unit fields as appropriate. Otherwise provide clarification ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 07:20:48
User entered 'I'	Diana Bahena (b) (4) (b) (4)	01 Oct 2020 15:02:56

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Marla Schwarber (b) (4)	22 Jan 2021 16:14:35
	(b) (4)	
User entered 'tablet (TABLET)'	Diana Bahena (b) (4)	01 Oct 2020 15:02:56
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered empty.	Diana Bahena (b) (4)	01 Oct 2020 15:02:56
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'once daily (QD)'	(b) (4) Diana Bahena (b) (4) (b) (4)	01 Oct 2020 15:02:56

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered empty.	Diana Bahena (b) (4)	01 Oct 2020 15:02:56
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Oral (ORAL)'	(b) (4) Diana Bahena (b) (4) (b) (4)	01 Oct 2020 15:02:56

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered empty.	Diana Bahena (b) (4)	01 Oct 2020 15:02:56
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:36

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'un UNK 2020'	Diana Bahena (b) (4)	01 Oct 2020 15:02:56
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered '0'	Diana Bahena (b) (4)	01 Oct 2020 15:02:56
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'Yes (Y)'	Diana Bahena (b) (4)	01 Oct 2020 15:02:56
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered empty.	Diana Bahena (b) (4)	01 Oct 2020 15:02:56
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'No (N)'	Diana Bahena (b) (4)	01 Oct 2020 15:02:56
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:02:56

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:02:56

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 15:02:56

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:36

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:00:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Dec 2020 19:05:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Dec 2020 19:05:54
Data point term sent to Coder	System	09 Dec 2020 23:43:30
Coding entries removed.	Marla Schwarber (b) (4)	09 Dec 2020 23:43:22
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 15:05:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 15:05:45
Data point term sent to Coder	System	01 Oct 2020 15:04:13
User entered 'Doxycycline'	Diana Bahena (b) (4)	01 Oct 2020 15:03:42

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:00:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'No (N)'	Diana Bahena (b) (4)	01 Oct 2020 15:03:42

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:00:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User closed query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 07:23:27
Query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' answered with 'MH updated' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	09 Dec 2020 23:43:33
User entered 'bilateral recurrent STYEs' reason for change: New Information	Marla Schwarber (b) (4) (b) (4)	09 Dec 2020 23:43:22
User opened query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 04:24:02
User entered 'Stye'	Diana Bahena (b) (4) (b) (4)	01 Oct 2020 15:03:42

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:00:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '50'	Diana Bahena (b) (4)	01 Oct 2020 15:03:42

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:00:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'mg (mg)'	Diana Bahena (b) (4)	01 Oct 2020 15:03:42

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:00:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	Diana Bahena (b) (4)	01 Oct 2020 15:03:42

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:00:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'as needed (PRN)'	Diana Bahena (b) (4)	01 Oct 2020 15:03:42

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:00:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	Diana Bahena (b) (4)	01 Oct 2020 15:03:42

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:00:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Oral (ORAL)'	Diana Bahena (b) (4)	01 Oct 2020 15:03:42

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:00:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	Diana Bahena (b) (4)	01 Oct 2020 15:03:42

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:36

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:00:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'un UNK 2014'	Diana Bahena (b) (4)	01 Oct 2020 15:03:42

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:00:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '0'	Diana Bahena (b) (4)	01 Oct 2020 15:03:42

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:00:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'No (N)'	Diana Bahena (b) (4)	01 Oct 2020 15:03:42

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:00:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'un Jun 2020'	Diana Bahena (b) (4)	01 Oct 2020 15:03:42

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:00:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'No (N)'	Diana Bahena (b) (4)	01 Oct 2020 15:03:42

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:00:10
User entered empty.	System	01 Oct 2020 15:03:42

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:00:10
User entered empty.	System	01 Oct 2020 15:03:42

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:00:10
User entered empty.	System	01 Oct 2020 15:03:42

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Feb 2021 11:04:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 11:04:51
Data point term sent to Coder Coding entries removed.	System Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:25:02 09 Feb 2021 15:24:15
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 12:09:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 12:09:22
Data point term sent to Coder User entered 'Diclofenac'	System (b) (4), (b) (6)	26 Jan 2021 17:33:28 26 Jan 2021 17:32:51

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:32:51

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'torn tendon left wrist' reason for change: Data Entry Error	Lorna Sanchez McCann	09 Feb 2021 15:24:15
	(b) (4)	
User entered 'Left Wrist Pain'	(b) (4), (b) (6)	26 Jan 2021 17:32:51

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered '50' reason for change: Data Entry Error	Lorna Sanchez McCann	09 Feb 2021 15:24:01
	(b) (4)	
User entered '5'	(b) (4), (b) (6)	26 Jan 2021 17:32:51

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:32:51

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:32:51

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:32:51

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:32:51

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:32:51

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:32:51

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:36

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '23 Dec 2020'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:32:51

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:32:51

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:32:51

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:32:51

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:32:51

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 17:32:51

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 17:32:51

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 17:32:51

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:36

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Feb 2021 08:39:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 08:39:44
Data point term sent to Coder Coding entries removed.	System Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:26:06 09 Feb 2021 15:25:43
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 12:05:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 12:05:00
Data point term sent to Coder User entered 'Cyclobenzaprine'	System (b) (4), (b) (6)	26 Jan 2021 17:36:32 26 Jan 2021 17:36:01

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:36:01

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:36

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 05:32:49
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'There is a AE that matches this, it is #3 on the AE list' (Site from DM).	Michelle Agnoli (b) (4)	19 Mar 2021 20:04:00
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 00:25:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'torn tendon left wrist' reason for change: Data Entry Error	(b) (4)	
User entered 'Left Wrist Pain'	Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:25:43
	(b) (4), (b) (6)	26 Jan 2021 17:36:01

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '5'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:36:01

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:36:01

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:36:01

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:36:01

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:36:01

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:36:01

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:36:01

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:36

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '23 Dec 2020'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:36:01

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:36:01

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Jan 2021 17:36:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Jan 2021 17:36:10
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 17:36:10
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Jan 2021 17:36:01
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 17:36:01

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:36:01

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:36:01

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 17:36:01

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 17:36:01

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 17:36:01

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: PREPARATIONS WITH SALICYLIC ACID DERIVATIVES, PRODUCT: MENTHOL;METHYL SALICYLATE, PRODUCTSYNONYM: SALONPAS [MENTHOL;METHYL SALICYLATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 12:07:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 12:07:54
Data point term sent to Coder	System	09 Feb 2021 15:29:08
User entered 'salompas (menthol 3%, methyl salicylate 10%)'	Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:28:11

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'No (N)'	Lorna Sanchez McCann	09 Feb 2021 15:28:11
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'torn tendon left wrist'	Lorna Sanchez McCann	09 Feb 2021 15:28:11
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '1'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:28:11

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'Other (OTHER)'	Lorna Sanchez McCann	09 Feb 2021 15:28:11
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'application'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:28:11

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'as needed (PRN)'	Lorna Sanchez McCann	09 Feb 2021 15:28:11
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered empty.	Lorna Sanchez McCann	09 Feb 2021 15:28:11
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'Topical (TOPICAL)'	Lorna Sanchez McCann	09 Feb 2021 15:28:11
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered empty.	Lorna Sanchez McCann	09 Feb 2021 15:28:11
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:36

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered '23 Dec 2020'	Lorna Sanchez McCann	09 Feb 2021 15:28:11
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered '0'	Lorna Sanchez McCann	09 Feb 2021 15:28:11
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'Yes (Y)'	Lorna Sanchez McCann	09 Feb 2021 15:28:11
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered empty.	Lorna Sanchez McCann	09 Feb 2021 15:28:11
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'No (N)'	Lorna Sanchez McCann	09 Feb 2021 15:28:11
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 15:28:11

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 15:28:11

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 15:28:11

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:36

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 13:36:42
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 13:36:42
	(b) (4)	
Data point term sent to Coder	System	11 Mar 2021 17:42:03
Coding entries removed.	Diana Bahena (b) (4)	11 Mar 2021 17:41:03
	(b) (4)	
Signature has been broken.	Diana Bahena (b) (4)	11 Mar 2021 17:41:03
	(b) (4)	
User entered 'LIDOCAINE 4% CREAM' reason for change: Data Entry Error	Diana Bahena (b) (4)	11 Mar 2021 17:41:03
	(b) (4)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Feb 2021 14:16:47
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Feb 2021 14:16:47
	(b) (4)	
Data point term sent to Coder	System	09 Feb 2021 15:29:08
User entered 'lidocaine cream'	Lorna Sanchez McCann	09 Feb 2021 15:29:04
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'No (N)'	Lorna Sanchez McCann	09 Feb 2021 15:29:04
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'torn tendon left wrist'	Lorna Sanchez McCann	09 Feb 2021 15:29:04
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 09:02:44
Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate. ' answered with 'updated' (Site from DM).	Diana Bahena (b) (4) (b) (4)	11 Mar 2021 17:41:37
Signature has been broken.	Diana Bahena (b) (4) (b) (4)	11 Mar 2021 17:41:03
User entered '1' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	11 Mar 2021 17:41:03
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 07:02:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:31:54
User entered '4'	Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:29:04

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'Other (OTHER)'	Lorna Sanchez McCann	09 Feb 2021 15:29:04
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
	(b) (4)	
Signature has been broken.	Diana Bahena (b) (4)	11 Mar 2021 17:41:03
	(b) (4)	
User entered 'application' reason for change: Data Entry Error	Diana Bahena (b) (4)	11 Mar 2021 17:41:03
	(b) (4)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered '%'	Lorna Sanchez McCann	09 Feb 2021 15:29:04
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'as needed (PRN)'	Lorna Sanchez McCann	09 Feb 2021 15:29:04
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered empty.	Lorna Sanchez McCann	09 Feb 2021 15:29:04
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'Topical (TOPICAL)'	Lorna Sanchez McCann	09 Feb 2021 15:29:04
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered empty.	Lorna Sanchez McCann	09 Feb 2021 15:29:04
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:36

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered '23 Dec 2020'	Lorna Sanchez McCann	09 Feb 2021 15:29:04
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered '0'	Lorna Sanchez McCann	09 Feb 2021 15:29:04
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'Yes (Y)'	Lorna Sanchez McCann	09 Feb 2021 15:29:04
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered empty.	Lorna Sanchez McCann	09 Feb 2021 15:29:04
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'No (N)'	Lorna Sanchez McCann	09 Feb 2021 15:29:04
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 15:29:04

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 15:29:04

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 15:29:04

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN, PRODUCTSYNONYM: NAPROXIN [NAPROXEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Feb 2021 13:59:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Feb 2021 13:59:55
Data point term sent to Coder	System	09 Feb 2021 15:30:09
User entered 'neproxin'	Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:29:44

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'No (N)'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:29:44

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered 'torn tendon left wrist'	Lorna Sanchez McCann	09 Feb 2021 15:29:44
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '500'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:29:44

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'mg (mg)'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:29:44

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:29:44

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'as needed (PRN)'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:29:44

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered empty.	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:29:44

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Oral (ORAL)'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:29:44

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered empty.	Lorna Sanchez McCann	09 Feb 2021 15:29:44
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:36

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '23 Dec 2020'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:29:44

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered '0'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:29:44

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:29:44

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
	(b) (4)	
User entered empty.	Lorna Sanchez McCann	09 Feb 2021 15:29:44
	(b) (4)	

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'No (N)'	(b) (4) Lorna Sanchez McCann (b) (4)	09 Feb 2021 15:29:44

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 15:29:44

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 15:29:44

US3492281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 15:29:44

US3492281

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:03:36

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:30
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:31:54
User entered 'Yes (Y)'	Diana Bahena (b) (4)	01 Oct 2020 15:03:56

US3492281

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:03:36

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
	(b) (4)	
User entered '04 Jan 2021'	Michelle Agnoli (b) (4)	11 Mar 2021 20:43:18
	(b) (4)	

US3492281

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:03:36

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
	(b) (4)	
User entered 'PHYSICAL THERAPY For Torn Tendon in Left Wrist' reason for change: Per Query Resolution	Michelle Agnoli (b) (4)	11 Mar 2021 20:47:01
	(b) (4)	
User entered 'Physical Therapy'	Michelle Agnoli (b) (4)	11 Mar 2021 20:43:18
	(b) (4)	

US3492281

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:03:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 05:35:20
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' answered with 'checked con procedure on AE ecrf to resolve query' (Site from DM).	Michelle Agnoli (b) (4) (b) (4)	19 Mar 2021 20:14:41
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 14:44:36
User entered 'Adverse Event (AE)'	Michelle Agnoli (b) (4) (b) (4)	11 Mar 2021 20:43:18

US3492281

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:03:36

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:30
	(b) (4)	
User entered empty.	Michelle Agnoli (b) (4)	11 Mar 2021 20:43:18
	(b) (4)	

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'USA-US101-2021-MRNA-1273-P301000007'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Yes (Y)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Yes (Y)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Richard'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Novak'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered '808 S. Wood St'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Chicago'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'IL'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered '60612'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:41:37
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'US'	(b) (4) System	10 Feb 2021 14:19:43

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	23 Apr 2021 14:23:36
User entered '6'	System	20 Apr 2021 13:32:43
User entered '5'	System	16 Apr 2021 13:15:32
User entered '4'	System	22 Mar 2021 17:20:19
User entered '3'	System	12 Mar 2021 13:41:49
Signature has been broken.	System	18 Feb 2021 16:40:02
User entered '2'	System	18 Feb 2021 16:40:02
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
	(b) (4)	
User entered '1'	System	10 Feb 2021 14:19:43

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'USA-US101-2021-MRNA-1273-P301000007'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Yes (Y)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Yes (Y)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Richard'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Novak'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered '808 S. Wood St'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Chicago'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'IL'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered '60612'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:41:37
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'US'	(b) (4) System	10 Feb 2021 14:19:43

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	23 Apr 2021 14:23:36
User entered '6'	System	20 Apr 2021 13:32:43
User entered '5'	System	16 Apr 2021 13:15:32
User entered '4'	System	22 Mar 2021 17:20:19
User entered '3'	System	12 Mar 2021 13:41:49
Signature has been broken.	System	18 Feb 2021 16:40:02
User entered '2'	System	18 Feb 2021 16:40:02
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
	(b) (4)	
User entered '1'	System	10 Feb 2021 14:19:43

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:03:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered '10/Feb/2021 09:19'	(b) (4) System	10 Feb 2021 14:19:43

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:03:36

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:41:37
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'I'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:43

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'USA-US101-2021-MRNA-1273-P301000007'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Yes (Y)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Yes (Y)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Richard'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Novak'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered '808 S. Wood St'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Chicago'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'IL'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered '60612'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:41:37
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'US'	(b) (4) System	10 Feb 2021 14:19:43

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	23 Apr 2021 14:23:36
User entered '6'	System	20 Apr 2021 13:32:43
User entered '5'	System	16 Apr 2021 13:15:32
User entered '4'	System	22 Mar 2021 17:20:19
User entered '3'	System	12 Mar 2021 13:41:49
Signature has been broken.	System	18 Feb 2021 16:40:02
User entered '2'	System	18 Feb 2021 16:40:02
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
	(b) (4)	
User entered '1'	System	10 Feb 2021 14:19:43

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:03:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:18:08
User entered '18/Feb/2021 11:39'	System	18 Feb 2021 16:40:02

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:03:36

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 13:41:37
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User entered 'I'	(b) (4), (b) (6)	18 Feb 2021 16:40:02

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'USA-US101-2021-MRNA-1273-P301000007'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Yes (Y)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Yes (Y)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Richard'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Novak'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered '808 S. Wood St'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Chicago'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'IL'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered '60612'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:41:37
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'US'	(b) (4) System	10 Feb 2021 14:19:43

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	23 Apr 2021 14:23:36
User entered '6'	System	20 Apr 2021 13:32:43
User entered '5'	System	16 Apr 2021 13:15:32
User entered '4'	System	22 Mar 2021 17:20:19
User entered '3'	System	12 Mar 2021 13:41:49
Signature has been broken.	System	18 Feb 2021 16:40:02
User entered '2'	System	18 Feb 2021 16:40:02
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
	(b) (4)	
User entered '1'	System	10 Feb 2021 14:19:43

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:03:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered '12/Mar/2021 13:41'	(b) (4) System	12 Mar 2021 13:41:49

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:03:36

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 13:32:32
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered 'I'	(b) (4), (b) (6)	12 Mar 2021 13:41:49

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'USA-US101-2021-MRNA-1273-P301000007'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Yes (Y)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Yes (Y)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Richard'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Novak'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered '808 S. Wood St'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Chicago'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'IL'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered '60612'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:41:37
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'US'	(b) (4) System	10 Feb 2021 14:19:43

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	23 Apr 2021 14:23:36
User entered '6'	System	20 Apr 2021 13:32:43
User entered '5'	System	16 Apr 2021 13:15:32
User entered '4'	System	22 Mar 2021 17:20:19
User entered '3'	System	12 Mar 2021 13:41:49
Signature has been broken.	System	18 Feb 2021 16:40:02
User entered '2'	System	18 Feb 2021 16:40:02
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
	(b) (4)	
User entered '1'	System	10 Feb 2021 14:19:43

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:03:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered '22/Mar/2021 13:20'	(b) (4) System	22 Mar 2021 17:20:19

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:03:36

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 13:32:32
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:56:31
User entered 'I'	(b) (4), (b) (6)	22 Mar 2021 17:20:19

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'USA-US101-2021-MRNA-1273-P301000007'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Yes (Y)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Yes (Y)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Richard'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Novak'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered '808 S. Wood St'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Chicago'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'IL'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered '60612'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:41:37
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'US'	(b) (4) System	10 Feb 2021 14:19:43

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	23 Apr 2021 14:23:36
User entered '6'	System	20 Apr 2021 13:32:43
User entered '5'	System	16 Apr 2021 13:15:32
User entered '4'	System	22 Mar 2021 17:20:19
User entered '3'	System	12 Mar 2021 13:41:49
Signature has been broken.	System	18 Feb 2021 16:40:02
User entered '2'	System	18 Feb 2021 16:40:02
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
	(b) (4)	
User entered '1'	System	10 Feb 2021 14:19:43

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:03:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:43
User entered '16/Apr/2021 06:15'	(b) (4) System	16 Apr 2021 13:15:32

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:03:36

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:43
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 13:32:32
User entered 'I'	(b) (4), (b) (6)	16 Apr 2021 13:15:32

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'USA-US101-2021-MRNA-1273-P301000007'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Yes (Y)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Yes (Y)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Richard'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Novak'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered '808 S. Wood St'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Chicago'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'IL'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered '60612'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:41:37
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'US'	(b) (4) System	10 Feb 2021 14:19:43

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	23 Apr 2021 14:23:36
User entered '6'	System	20 Apr 2021 13:32:43
User entered '5'	System	16 Apr 2021 13:15:32
User entered '4'	System	22 Mar 2021 17:20:19
User entered '3'	System	12 Mar 2021 13:41:49
Signature has been broken.	System	18 Feb 2021 16:40:02
User entered '2'	System	18 Feb 2021 16:40:02
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
	(b) (4)	
User entered '1'	System	10 Feb 2021 14:19:43

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:03:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:43
User entered '20/Apr/2021 09:32'	(b) (4) System	20 Apr 2021 13:32:43

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:03:36

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:43
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 14:22:37
User entered 'I'	(b) (4), (b) (6)	20 Apr 2021 13:32:43

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'USA-US101-2021-MRNA-1273-P301000007'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Yes (Y)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Yes (Y)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

US3492281

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'No (N)'	System	10 Feb 2021 14:19:15

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Richard'	System	10 Feb 2021 14:19:15

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Novak'	System	10 Feb 2021 14:19:15

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Folder: SAE USA-US101-2021-MRNA-1273-P301000007

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[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered '808 S. Wood St'	System	10 Feb 2021 14:19:15

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Folder: SAE USA-US101-2021-MRNA-1273-P301000007

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[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'Chicago'	System	10 Feb 2021 14:19:15

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[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered 'IL'	System	10 Feb 2021 14:19:15

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[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:19:31
User entered '60612'	System	10 Feb 2021 14:19:15

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[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 13:41:37
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:18:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
User entered 'US'	(b) (4) System	10 Feb 2021 14:19:43

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Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	23 Apr 2021 14:23:36
User entered '6'	System	20 Apr 2021 13:32:43
User entered '5'	System	16 Apr 2021 13:15:32
User entered '4'	System	22 Mar 2021 17:20:19
User entered '3'	System	12 Mar 2021 13:41:49
Signature has been broken.	System	18 Feb 2021 16:40:02
User entered '2'	System	18 Feb 2021 16:40:02
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:32:17
	(b) (4)	
User entered '1'	System	10 Feb 2021 14:19:43

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Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:03:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:43
User entered '23/Apr/2021 10:23'	(b) (4) System	23 Apr 2021 14:23:36

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Folder: SAE USA-US101-2021-MRNA-1273-P301000007

Form: Safety Report Form (7)

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Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:43
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:23:36