

US3492061 (Prod: UIC Project WISH CRS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:50:42

All time stamps listed in this document are displayed in GMT

US3492061

Form: Participant Creation

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

[Participant ID](#)

US3492061

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

US3492061

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

Date of Birth (MMM yyyy)	(b) (6) 1990
Age	30
Age Units	YEARS
Age (Derived)	30
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	True
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

Date of Informed Consent (<i>dd MMM yyyy</i>)	4 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input 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 03:35:50

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 03:35:50

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 03:35:50

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Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

Condition	
Start date (dd MMM yyyy)	
Start date completely unknown	
Condition ongoing at study entry	Yes <input type="checkbox"/> No <input type="checkbox"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	4 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:30 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 09:30
Height (<i>xxx.x</i>)	167 cm
Weight (<i>xxx.x</i>)	56.6 kg
BMI (<i>xxx.x</i>)	20.29474 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 03:35:50

Generated On: 11 Aug 2021 22:50:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 03:35:50

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

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	4 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 03:35:50

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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 03:35:50

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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) 26 Mar 2021 01:40:44

Generated On: 11 Aug 2021 22:50:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 03:35:56

Generated On: 11 Aug 2021 22:50:42

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

What was the participant's randomization number? 111797

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) 26 Mar 2021 01:40:44

Generated On: 11 Aug 2021 22:50:42

Height	ND - Not Done
Weight	ND - Not Done

US3492061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 01:40:44

Generated On: 11 Aug 2021 22:50:42

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)	04 SEP 2020
Time of assessment (00:00-23:59)	09:07 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 09:07
Temperature (xxx.x)	35.2 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	EAR
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	91 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Mar 2021 01:40:44

Generated On: 11 Aug 2021 22:50:42

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)	04 SEP 2020
Time of assessment (00:00-23:59)	9:30 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 9:30
Temperature (xxx.x)	35.2 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	EAR
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 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 03:35:50

Generated On: 11 Aug 2021 22:50:42

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 03:35:56

Generated On: 11 Aug 2021 22:50:42

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 01:40:44

Generated On: 11 Aug 2021 22:50:42

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 4 SEP 2020

What was the treatment time? (00:00-23:59) 09:22 (24 HR)

Treatment Date and Time (derived) 4 SEP 2020 09:22

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) 26 Mar 2021 01:40:44

Generated On: 11 Aug 2021 22:50:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

04 SEP 2020

Collection time (00:00-23:59)

10:20 (24 HR)

Collection date and time (derived)

04 SEP 2020 10:20

US3492061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

Collection date (dd MMM yyyy)			4 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:30	4 SEP 2020 10:30
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 95.4 °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):

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

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

PC Time Stamp 05 SEP 2020 09:44

PC Open Date & Time 05 SEP 2020 09:42

PC Close Date & Time 05 SEP 2020 12:12

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.2 °F

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

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

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

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

PC Time Stamp 05 SEP 2020 23:43

PC Open Date & Time 05 SEP 2020 13:07

PC Close Date & Time 06 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

06 SEP 2020 21:26

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:50:42

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 22:11

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:50:42

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

97.5 °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

08 SEP 2020 22:18

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:50:42

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 22:19

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:50:42

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 22:49

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:50:42

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

97.2 °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

11 SEP 2020 21:27

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

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

05 SEP 2020 09:45

PC Open Date & Time

05 SEP 2020 09:42

PC Close Date & Time

05 SEP 2020 12:12

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☒

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 23:43

PC Open Date & Time

05 SEP 2020 13:07

PC Close Date & Time

06 SEP 2020 11:59

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 21:26

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 22:11

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:50:42

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

08 SEP 2020 22:18

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:50:42

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

09 SEP 2020 22:18

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:50:42

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

10 SEP 2020 22:48

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:50:42

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

11 SEP 2020 21:27

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

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 ☐

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

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

No ☒

Yes ☐

PC Time stamp	05 SEP 2020 09:45
PC Open Date & Time	05 SEP 2020 09:42
PC Close Date & Time	05 SEP 2020 12:12

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

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 ☐

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

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

No ☒

Yes ☐

PC Time stamp	05 SEP 2020 23:44
PC Open Date & Time	05 SEP 2020 13:07
PC Close Date & Time	06 SEP 2020 11:59

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:50:42

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 ☒

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:50:42

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 21:26
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:50:42

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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EAB) (1725)

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:50:42

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

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:50:42

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 ☒

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:50:42

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 22:18
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:50:42

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 ☒

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US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:50:42

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 22:18
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:50:42

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 ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:50:42

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 22:48
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:50:42

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 ☒

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:50:42

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 21:27
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3492061

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492061

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492061

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

Was Contact Attempted? Yes ☒ No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 SEP 2020

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

Comments 09/18/20 LEFT A MESSAGE.
ELENA
If Contact Not Made, please provide Comments 09/21/20 CONTACT MADE

US3492061

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492061

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492061

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492061

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:35:57

Generated On: 11 Aug 2021 22:50:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 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

US3492061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 03:35:57

Generated On: 11 Aug 2021 22:50:42

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)	5 OCT 2020
Time of assessment (00:00-23:59)	15:21 (24 HR)
Vital Signs Date and Time (derived)	5 OCT 2020 15:21
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)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 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

US3492061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 03:35:57

Generated On: 11 Aug 2021 22:50:42

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)	5 OCT 2020
Time of assessment (00:00-23:59)	16:28 (24 HR)
Vital Signs Date and Time (derived)	5 OCT 2020 16:28
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)	64 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)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3492061

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 03:35:57

Generated On: 11 Aug 2021 22:50:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 OCT 2020

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

US3492061

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 03:35:57

Generated On: 11 Aug 2021 22:50:42

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	5 OCT 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3492061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 03:35:57

Generated On: 11 Aug 2021 22:50:42

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) 5 OCT 2020

What was the treatment time? (00:00-23:59) 16:20 (24 HR)

Treatment Date and Time (derived) 5 OCT 2020 16:20

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

What was the frequency of the study treatment dosing? ONCE

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

US3492061

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 03:35:57

Generated On: 11 Aug 2021 22:50:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

5 OCT 2020

Collection time (00:00-23:59)

15:40 (24 HR)

Collection date and time (derived)

5 OCT 2020 15:40

US3492061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 03:35:57

Generated On: 11 Aug 2021 22:50:42

Collection date (dd MMM yyyy)			5 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:50	5 OCT 2020 15:50
Nasopharyngeal Swab 2	No		

US3492061

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:35:57

Generated On: 11 Aug 2021 22:50:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

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 ☒

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 19:05

PC Open Date & Time 05 OCT 2020 16:40

PC Close Date & Time 05 OCT 2020 19:10

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

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

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 05 OCT 2020 20:05

PC Close Date & Time 06 OCT 2020 11:59

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

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

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

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

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:50:42

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 22:41

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:50:42

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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 OCT 2020 09:45

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 OCT 2020 20:00

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:50:42

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

97.4 °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

10 OCT 2020 23:42

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

11 OCT 2020 20:01

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

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

05 OCT 2020 19:05

PC Open Date & Time

05 OCT 2020 16:40

PC Close Date & Time

05 OCT 2020 19:10

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

05 OCT 2020 20:05

PC Close Date & Time

06 OCT 2020 11:59

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☒

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 20:08

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 22:41

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:50:42

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

09 OCT 2020 09:45

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:50:42

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

09 OCT 2020 20:00

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:50:42

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

10 OCT 2020 23:42

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:50:42

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

11 OCT 2020 20:01

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

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 ☐

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

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

No ☒

Yes ☐

PC Time stamp	05 OCT 2020 19:05
PC Open Date & Time	05 OCT 2020 16:40
PC Close Date & Time	05 OCT 2020 19:10

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

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 ☐

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

05 OCT 2020 20:05

PC Close Date & Time

06 OCT 2020 11:59

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:50:42

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 ☒

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:50:42

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 20:08
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:50:42

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 ☒

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:50:42

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 22:42
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:50:42

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 ☒

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:50:42

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 09:45
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:50:42

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 ☒

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:50:42

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 20:00
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:50:42

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 ☒

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US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:50:42

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 23:42
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:50:42

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 ☒

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:50:42

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 20:02
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3492061

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492061

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492061

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492061

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492061

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492061

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492061

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:35:57

Generated On: 11 Aug 2021 22:50:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 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

US3492061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 03:35:57

Generated On: 11 Aug 2021 22:50:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 NOV 2020
Time of assessment (00:00-23:59)	12:50 (24 HR)
Vital Signs Date and Time (derived)	2 NOV 2020 12:50
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492061

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 03:35:57

Generated On: 11 Aug 2021 22:50:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 NOV 2020

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

US3492061

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 03:35:57

Generated On: 11 Aug 2021 22:50:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 NOV 2020

Collection time (00:00-23:59)

13:00 (24 HR)

Collection date and time (derived)

2 NOV 2020 13:00

US3492061

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:35:57

Generated On: 11 Aug 2021 22:50:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

Patient Cloud Open Date & Time

05 NOV 2020 00:01

Patient Cloud Close Date & Time

09 NOV 2020 23:59

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

Patient Cloud Open Date & Time

12 NOV 2020 00:01

Patient Cloud Close Date & Time

16 NOV 2020 23:59

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

[Patient Cloud Close Date & Time](#)

27 NOV 2020 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

[Patient Cloud Close Date & Time](#)

04 DEC 2020 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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	07 DEC 2020 07:12:37
Patient Cloud Open Date & Time	07 DEC 2020 00:01
Patient Cloud Close Date & Time	11 DEC 2020 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 <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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

18 DEC 2020 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01
Patient Cloud Close Date & Time	25 DEC 2020 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

[Patient Cloud Close Date & Time](#)

01 JAN 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 JAN 2021 11:12:39
Patient Cloud Open Date & Time	04 JAN 2021 00:01
Patient Cloud Close Date & Time	08 JAN 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

15 JAN 2021 20:12:34

Patient Cloud Open Date & Time

11 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

20 JAN 2021 13:00:50

Patient Cloud Open Date & Time

18 JAN 2021 00:01

Patient Cloud Close Date & Time

22 JAN 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 JAN 2021 22:14:22
Patient Cloud Open Date & Time	25 JAN 2021 00:01
Patient Cloud Close Date & Time	29 JAN 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

03 FEB 2021 17:35:56

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

12 FEB 2021 07:09:33

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

19 FEB 2021 17:39:49

Patient Cloud Open Date & Time

15 FEB 2021 00:01

Patient Cloud Close Date & Time

19 FEB 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

23 FEB 2021 15:53:14

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAR 2021 17:52:49
Patient Cloud Open Date & Time	01 MAR 2021 00:01
Patient Cloud Close Date & Time	05 MAR 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

11 MAR 2021 15:54:29

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 MAR 2021 08:39:33

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAR 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

01 APR 2021 15:46:26

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

09 APR 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

16 APR 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 14:59:58

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 10:45:29

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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="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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAY 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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="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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 <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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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="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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 <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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 <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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

[Patient Cloud Close Date & Time](#)

16 JUL 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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="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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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="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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 <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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 <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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 <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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 <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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 <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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

[Patient Cloud Close Date & Time](#)

15 OCT 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

29 OCT 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 <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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 ☐

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 <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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

19 NOV 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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="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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 ☐

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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="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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	24 DEC 2021 23:59
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US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 <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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

31 DEC 2021 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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="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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 <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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 ☐

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 <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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 <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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 <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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 ☐

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 ☐

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 <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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 <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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 <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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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="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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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="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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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="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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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="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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

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10 JUN 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2022 00:01

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17 JUN 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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="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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

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24 JUN 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 ☐

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

Date and time of submission

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27 JUN 2022 00:01

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01 JUL 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

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04 JUL 2022 00:01

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08 JUL 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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="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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01

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22 JUL 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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="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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01

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05 AUG 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 <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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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 AUG 2022 00:01

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12 AUG 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 <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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 <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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 <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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

[Patient Cloud Close Date & Time](#)

21 OCT 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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 <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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

[Patient Cloud Close Date & Time](#)

04 NOV 2022 23:59

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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"/>

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2022 23:59

US3492061

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:50:42

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 17:52:42

US3492061

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492061

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492061

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492061

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492061

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:40:44

Generated On: 11 Aug 2021 22:50:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492061

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:40:44

Generated On: 11 Aug 2021 22:50:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492061

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:40:44

Generated On: 11 Aug 2021 22:50:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492061

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:40:44

Generated On: 11 Aug 2021 22:50:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492061

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 16:22:37

Generated On: 11 Aug 2021 22:50:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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	VISIT4

US3492061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 16:22:37

Generated On: 11 Aug 2021 22:50:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 MAR 2021
Time of assessment (00:00-23:59)	08:55 (24 HR)
Vital Signs Date and Time (derived)	29 MAR 2021 08:55
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)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492061

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 16:22:37

Generated On: 11 Aug 2021 22:50:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 MAR 2021

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

US3492061

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 16:22:37

Generated On: 11 Aug 2021 22:50:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 MAR 2021

Collection time (00:00-23:59)

09:05 (24 HR)

Collection date and time (derived)

29 MAR 2021 09:05

US3492061

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 16:22:37

Generated On: 11 Aug 2021 22:50:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492061

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 30 Apr 2021 21:44:49

Generated On: 11 Aug 2021 22:50:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492061

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 30 Apr 2021 21:44:49

Generated On: 11 Aug 2021 22:50:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492061

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

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

US3492061

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3492061

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:50:42

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"/>

US3492061

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:50:42

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3492061

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

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

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

Visit date (dd MMM yyyy)	20 JAN 2021
--------------------------	-------------

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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US3492061

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

Form: Unblinding

Data signed: (b) (4) 26 Mar 2021 01:40:44

Generated On: 11 Aug 2021 22:50:42

Date of updated informed consent (dd MMM yyyy) 20 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 20 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3492061

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 JAN 2021

Collection time (00:00-23:59)

13:20 (24 HR)

Collection date and time (derived)

20 JAN 2021 13:20

US3492061

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 JAN 2021
Collection time (00:00 - 23:59)	13:25
Collection Date and Time (derived)	20 JAN 2021 13:25

US3492061

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Apr 2021 16:22:37

Generated On: 11 Aug 2021 22:50:42

Did the participant experience any adverse events?

Yes ☐

No ☒

If Yes, enter details on the Adverse Events form.

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

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

Yes ☒

No ☐

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

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 16:22:37

Generated On: 11 Aug 2021 22:50:42

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 16:22:37

Generated On: 11 Aug 2021 22:50:42

	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 2012
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"/>

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 16:22:37

Generated On: 11 Aug 2021 22:50:42

Name of Medication LILETTA (LEVONORGESTREL)
IUD

Prophylaxis Yes ☒
No ☐

Indication CONTRACEPTION

Dose per administration 52

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 16:22:37

Generated On: 11 Aug 2021 22:50:42

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INTRAUTERINE	
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	22 FEB 2021	
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"/>

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 16:22:37

Generated On: 11 Aug 2021 22:50:42

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 16:22:37

Generated On: 11 Aug 2021 22:50:42

	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)		05 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 05 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 16:22:37

Generated On: 11 Aug 2021 22:50:42

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication PAIN AT INJECTION SITE

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 16:22:37

Generated On: 11 Aug 2021 22:50:42

	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)	6 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy) 7 OCT 2020		
Was this medication taken for solicited event?	Yes <input checked="" type="checkbox"/>	
	No <input type="checkbox"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

US3492061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 15 Feb 2021 03:35:50

Generated On: 11 Aug 2021 22:50:42

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3492061

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:50:42

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

US3492061

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:50:42

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 ☐

Audit

US3492061 (Prod: UIC Project WISH CRS)

US3492061

Form: Participant Creation

Generated On: 11 Aug 2021 22:50:42

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'US3492061'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	04 Sep 2020 14:24:37

US3492061

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:50:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 16:12:38

US3492061

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '04 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	04 Sep 2020 14:24:38

US3492061

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:12:38

US3492061

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:50:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User entered 'SCRN'	(b) (4), (b) (6) System	04 Sep 2020 16:12:38

US3492061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:50:42

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered (b) (6) 1990'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	04 Sep 2020 14:24:39

US3492061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:50:42

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered '30'	(b) (4), (b) (6)	04 Sep 2020 16:13:31

US3492061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:50:42

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User entered 'YEARS'	(b) (4), (b) (6) System	04 Sep 2020 16:13:31

US3492061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:50:42

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User entered '30'	(b) (4), (b) (6) System	04 Sep 2020 16:14:27

US3492061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:50:42

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'Female (F)'	(b) (4), (b) (6)	04 Sep 2020 16:13:31

US3492061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:50:42

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	04 Sep 2020 16:13:31

US3492061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:50:42

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 16:13:31

US3492061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:50:42

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 16:13:31

US3492061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:50:42

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	04 Sep 2020 16:13:31

US3492061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:50:42

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 16:13:31

US3492061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:50:42

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 16:13:31

US3492061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:50:42

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 16:13:31

US3492061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:50:42

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:13:31

US3492061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:50:42

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 16:13:31

US3492061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:50:42

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 16:13:31

US3492061

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 16:14:27

US3492061

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User entered 'Sep 2020'	(b) (4), (b) (6) System	04 Sep 2020 16:14:27

US3492061

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User entered '2020'	(b) (4), (b) (6) System	04 Sep 2020 16:14:27

US3492061

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:50:42

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	04 Sep 2020 16:14:27

US3492061

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 16:14:27

US3492061

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:14:27

US3492061

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:50:42

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:14:27

US3492061

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:50:42

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Sep 2020 15:04:37
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 16:14:27

US3492061

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:50:42

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User closed query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	(b) (4) System	05 Sep 2020 15:04:37
User opened query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	System	04 Sep 2020 16:14:27
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	04 Sep 2020 14:24:38

US3492061

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:50:42

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User entered 'I'	(b) (4), (b) (6) System	04 Sep 2020 16:14:35

US3492061

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:14:35

US3492061

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:50:42

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:14:56

US3492061

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:50:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	11 Sep 2020 20:27:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 20:27:41
Data point term sent to Coder	System	11 Sep 2020 20:26:45
User closed query 'DM-Coding: please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding. Is this Gastrointestinal fullness/Gastrointestinal upset/Gastrointestinal bleeding and etc.' (Site from System).	System	11 Sep 2020 20:26:02
Query 'DM-Coding: please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding. Is this Gastrointestinal fullness/Gastrointestinal upset/Gastrointestinal bleeding and etc.' answered with 'Corrected' (Site from System).	Marla Schwarber (b) (4) (b) (4)	11 Sep 2020 20:26:02
User entered 'Gastroesophageal reflux disease' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	11 Sep 2020 20:25:53
User opened query 'DM-Coding: please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding. Is this Gastrointestinal fullness/Gastrointestinal upset/Gastrointestinal bleeding and etc.' (Site from System).	Coder Import (b) (4) (b) (4)	07 Sep 2020 14:33:41
Data point term sent to Coder	System	04 Sep 2020 16:16:24
User entered 'Gastrointestinal'	(b) (4), (b) (6)	04 Sep 2020 16:16:00

US3492061

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:50:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	04 Sep 2020 16:18:32
User entered 'UN UNK 2012' reason for change: Per Query Resolution	(b) (4), (b) (6)	04 Sep 2020 16:18:32
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Sep 2020 16:18:00
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Sep 2020 16:18:00
User entered '00 UNK 2012' (non-conformant).	(b) (4), (b) (6)	04 Sep 2020 16:18:00
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Sep 2020 16:17:24
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Sep 2020 16:17:24
User entered ' UNK 2012' (non-conformant).	(b) (4), (b) (6)	04 Sep 2020 16:17:24
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Sep 2020 16:16:00
User entered ' UNK 2010' (non-conformant).	(b) (4), (b) (6)	04 Sep 2020 16:16:00

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Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:50:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:16:00

US3492061

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:50:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	(b) (4) System	04 Sep 2020 16:17:50
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	04 Sep 2020 16:17:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 16:16:00

US3492061

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:16:00

US3492061

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:50:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered '0' reason for change: Per Query Resolution	(b) (4), (b) (6)	04 Sep 2020 16:17:50
User entered '1' reason for change: Per Query Resolution	(b) (4), (b) (6)	04 Sep 2020 16:17:24
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 16:16:00

US3492061

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User entered 'Jan 2012'	System	04 Sep 2020 16:18:32
User entered empty.	System	04 Sep 2020 16:16:00

US3492061

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User entered '2012'	System	04 Sep 2020 16:18:32
User entered empty.	System	04 Sep 2020 16:16:00

US3492061

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User entered empty.	(b) (4), (b) (6) System	04 Sep 2020 16:16:00

US3492061

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User entered empty.	(b) (4), (b) (6) System	04 Sep 2020 16:16:00

US3492061

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:50:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	11 Sep 2020 20:40:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 20:40:47
Data point term sent to Coder	System	11 Sep 2020 20:39:19
User entered 'Depression'	Andrea Wendrow (b) (4) (b) (4)	11 Sep 2020 20:39:17

US3492061

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'UN UNK 2016'	(b) (4) Andrea Wendrow (b) (4)	11 Sep 2020 20:39:17

US3492061

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:50:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered '0'	Andrea Wendrow (b) (4)	11 Sep 2020 20:39:17
	(b) (4)	

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Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:50:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Yes (Y)'	(b) (4) Andrea Wendrow (b) (4)	11 Sep 2020 20:39:17

US3492061

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	11 Sep 2020 20:39:17
	(b) (4)	

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Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:50:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	11 Sep 2020 20:39:17

US3492061

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User entered 'Jan 2016'	(b) (4), (b) (6) System	11 Sep 2020 20:39:17

US3492061

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User entered '2016'	(b) (4), (b) (6) System	11 Sep 2020 20:39:17

US3492061

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User entered empty.	(b) (4), (b) (6) System	11 Sep 2020 20:39:17

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Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User entered empty.	(b) (4), (b) (6) System	11 Sep 2020 20:39:17

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:50:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 20:02:29

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:50:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 20:02:29

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:50:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 20:02:29

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 20:02:29

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:50:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:50:42

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 20:02:29

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 20:02:29

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 16:20:28

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '4 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:20:28

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered '09:30'	(b) (4), (b) (6)	04 Sep 2020 16:20:28

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User entered '4 Sep 2020 09:30'	(b) (4), (b) (6) System	04 Sep 2020 16:20:28

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered '167' cm	(b) (4), (b) (6)	04 Sep 2020 16:20:28
DataPoint set to visible.	System	04 Sep 2020 16:14:35

US3492061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered '56.6' kg	(b) (4), (b) (6)	04 Sep 2020 16:20:28
DataPoint set to visible.	System	04 Sep 2020 16:14:35

US3492061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User entered '20.29474'	System	04 Sep 2020 16:20:28
DataPoint set to visible.	System	04 Sep 2020 16:14:35

US3492061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User entered 'kg/m2'	System	04 Sep 2020 16:20:28
DataPoint set to visible.	System	04 Sep 2020 16:14:35

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User closed query 'Per CDM: Thank you for updating the Temperature. However, please remove the unit, 'C'. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 05:16:24
Query 'Per CDM: Thank you for updating the Temperature. However, please remove the unit, 'C'. Thank you.' answered with 'Corrected' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	21 Sep 2020 21:57:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4) (b) (4)	21 Sep 2020 21:57:26
User opened query 'Per CDM: Thank you for updating the Temperature. However, please remove the unit, 'C'. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 17:32:28
User closed query 'Per CDM: Response noted; However as per CCGs pages 15-16, 'ND' should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP in Vital sign Screening page. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 10:32:45
Query 'Per CDM: Response noted; However as per CCGs pages 15-16, 'ND' should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP in Vital sign Screening page. Please update accordingly.' answered with 'Corrected' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	11 Sep 2020 20:27:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4) (b) (4)	11 Sep 2020 20:27:25
User opened query 'Per CDM: Response noted; However as per CCGs pages 15-16, 'ND' should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP in Vital sign Screening page. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 15:04:44
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 15:04:02
Query 'Data is required. Please provide.' answered with 'Taken at Visit 1' (Site from System).	(b) (4), (b) (6)	04 Sep 2020 16:20:58
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 16:20:28

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EAB) (1725)

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:20:28

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:20:28

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:20:28

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4)	11 Sep 2020 20:27:25
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 15:04:03
Query 'Data is required. Please provide.' answered with 'taken at visit 1' (Site from System).	(b) (4), (b) (6)	04 Sep 2020 16:21:09
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 16:20:28
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:20:28

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User entered 'bpm'	System	11 Sep 2020 20:27:25
User entered empty.	System	04 Sep 2020 16:20:28

US3492061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4)	11 Sep 2020 20:27:25
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 15:04:06
Query 'Data is required. Please provide.' answered with 'taken at visit 1' (Site from System).	(b) (4), (b) (6)	04 Sep 2020 16:21:19
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 16:20:28
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:20:28

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User entered 'breaths/min'	System	11 Sep 2020 20:27:25
User entered empty.	System	04 Sep 2020 16:20:28

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4)	11 Sep 2020 20:27:25
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 15:04:07
Query 'Data is required. Please provide.' answered with 'taken at visit 1' (Site from System).	(b) (4), (b) (6)	04 Sep 2020 16:21:27
User opened query 'Data is required. Please provide.' System (Site from System).		04 Sep 2020 16:20:28
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:20:28

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User entered 'mmHg'	System	11 Sep 2020 20:27:25
User entered empty.	System	04 Sep 2020 16:20:28

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4)	11 Sep 2020 20:27:25
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 15:04:10
Query 'Data is required. Please provide.' answered with 'taken at visit 1' (Site from System).	(b) (4), (b) (6)	04 Sep 2020 16:21:37
User opened query 'Data is required. Please provide.' System (Site from System).		04 Sep 2020 16:20:28
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:20:28

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User entered 'mmHg'	System	11 Sep 2020 20:27:25
User entered empty.	System	04 Sep 2020 16:20:28

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 20:02:29

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 20:02:29

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Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:50:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:22:02

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Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:50:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 16:22:02

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '4 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:22:49

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:50:42

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:22:49

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:50:42

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:22:49

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:50:42

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:22:49

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:22:49

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:50:42

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 16:22:49

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:22:49

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:50:42

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 16:22:49

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Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:50:42

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User closed query 'Was the pregnancy test performed is No, however data has been provided below. Please correct.' (Site from System).	System	04 Sep 2020 16:24:19
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4), (b) (6)	04 Sep 2020 16:24:19
User opened query 'Was the pregnancy test performed is No, however data has been provided below. Please correct.' (Site from System).	System	04 Sep 2020 16:23:30
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 16:23:30

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Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:50:42

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '4 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:23:30

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Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:50:42

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'Urine (URINE)'	(b) (4), (b) (6)	04 Sep 2020 16:23:30

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Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:50:42

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	04 Sep 2020 16:23:30

US3492061

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:50:42

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 16:23:30

US3492061

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:50:42

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:23:30

US3492061

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:50:42

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:23:30

US3492061

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User entered empty.	(b) (4), (b) (6) System	04 Sep 2020 16:23:30

US3492061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:25:40

US3492061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:25:40

US3492061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:25:40

US3492061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:25:40

US3492061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 16:25:40

US3492061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:25:40

US3492061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:25:40

US3492061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:25:40

US3492061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:25:40

US3492061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:25:40

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:25:40

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:50:42

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 16:25:40

US3492061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:50:42

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:25:40

US3492061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:50:42

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:25:40

US3492061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:50:42

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:25:40

US3492061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:25:40

US3492061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:25:40

US3492061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:25:40

US3492061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:25:40

US3492061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:50:42

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 16:25:40

US3492061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:50:42

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:25:40

US3492061

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:50:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:26:48

US3492061

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:50:42

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:44
Signature has been broken.	(b) (4) Gizelle Alvarez (b) (4)	03 Mar 2021 19:51:41
User entered '04 Sep 2020' reason for change: Per Query Resolution	Gizelle Alvarez (b) (4)	03 Mar 2021 19:51:41
User signature succeeded.	(b) (4) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered '05 Sep 2020' reason for change: Per Query Resolution	(b) (4) Andrea Wendrow (b) (4)	19 Oct 2020 19:55:50
User closed query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	15 Oct 2020 08:43:30
Query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' answered with 'This is correct. Subject came in 04Sep2020 and had all elements of visit up to randomization completed and realized had to leave for work related issue. Came in 05Sep2020 to complete rest of visit' (Site from System).	Andrea Wendrow (b) (4)	13 Oct 2020 18:53:36
User opened query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' (Site from System).	System	13 Oct 2020 18:52:12
User entered '04 Sep 2020' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	13 Oct 2020 18:52:12
User entered '5 Sep 2020' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	13 Oct 2020 18:50:10
User closed query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 15:03:00
Query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' answered with 'screen visit on 04Sep2020, began Visit 1 Day 1 activities on 04Sep2020, was randomized and then reported to staff she could not stay for injection as had work related activity that could not be rescheduled. Returned on 05Sep2020 to receive study injection and complete rest of visit' (Site from System).	Andrea Wendrow (b) (4)	05 Sep 2020 15:11:13

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
User opened query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' (Site from System).	System	05 Sep 2020 14:28:00
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 16:26:48

US3492061

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:26:48

US3492061

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:50:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User entered 'VISIT1'	(b) (4), (b) (6) System	04 Sep 2020 16:26:48

US3492061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User closed query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 13:34:33
Query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' answered with 'Subject randomized on 04Sep2020. Realized had to leave prior to injection for unavoidable work appointment. Returned next day for injection and rest of Day 1 visit.' (Site from System).	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:57:20
User opened query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Oct 2020 19:55:50
User closed query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Oct 2020 18:52:12
Query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	13 Oct 2020 18:52:12
User opened query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Oct 2020 18:50:10
User closed query 'The Randomization Date is not equal to first dose of study drug on the Exposure Form. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 15:01:27
Query 'The Randomization Date is not equal to first dose of study drug on the Exposure Form. Please review and reconcile.' answered with 'screen visit on 04Sep2020, began Visit 1 Day 1 activities on 04Sep2020, was randomized and then reported to staff she could not stay for injection as had work related activity that could not be rescheduled. Returned on 05Sep2020 to receive study injection and complete rest of visit' (Site from System).	Andrea Wendrow (b) (4) (b) (4)	05 Sep 2020 15:10:06
User opened query 'The Randomization Date is not equal to first dose of study drug on the Exposure Form. Please review and reconcile.' (Site from System).	System	05 Sep 2020 14:28:00

US3492061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	04 Sep 2020 15:39:58

US3492061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:50:42

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered '111797'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	04 Sep 2020 15:39:58

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	04 Sep 2020 15:39:58

US3492061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	04 Sep 2020 16:27:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 16:27:21
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	04 Sep 2020 16:27:21
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 16:27:02
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:27:02

US3492061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	04 Sep 2020 16:27:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 16:27:21
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	04 Sep 2020 16:27:21
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 16:27:02
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:27:02

US3492061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 16:27:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 16:27:21
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	04 Sep 2020 16:27:21
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 16:27:02
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:27:02

US3492061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:50:42

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 16:27:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 16:27:21
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	04 Sep 2020 16:27:21
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 16:27:02
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:27:02

US3492061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:50:42

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 16:27:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 16:27:21
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	04 Sep 2020 16:27:21
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 16:27:02
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:27:02

US3492061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:50:42

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	04 Nov 2020 19:46:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Nov 2020 19:46:25
User entered 'No (N)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	04 Nov 2020 19:46:25
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 19:57:13
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:57:13
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:06:54
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:22:16

US3492061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:50:42

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 05:16:45
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' answered with 'Corrected' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	21 Sep 2020 17:39:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4) (b) (4)	21 Sep 2020 17:39:17
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 17:32:42
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:28:40

US3492061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:50:42

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered missing code ND - Not Done; reason for	Marla Schwarber (b) (4)	21 Sep 2020 17:39:17
change Data Entry Error	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:28:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:50:42

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 05:16:45
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' answered with 'Corrected' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	21 Sep 2020 17:39:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4) (b) (4)	21 Sep 2020 17:39:17
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 17:32:42
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:28:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:50:42

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered missing code ND - Not Done; reason for	Marla Schwarber (b) (4)	21 Sep 2020 17:39:17
change Data Entry Error	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:28:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) (b) (4), (b) (6)	04 Sep 2020 16:28:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 14:34:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 14:34:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Sep 2020 14:34:13
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 16:28:40
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:28:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:44
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	03 Mar 2021 19:52:01
Signature has been broken.	Gizelle Alvarez (b) (4)	03 Mar 2021 19:52:01
User entered '04 Sep 2020' reason for change: Per Query Resolution	(b) (4) Gizelle Alvarez (b) (4)	03 Mar 2021 19:52:01
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	03 Mar 2021 19:51:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	19 Oct 2020 19:55:50
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Oct 2020 18:52:12
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Oct 2020 18:50:10
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	11 Sep 2020 20:31:07
User entered '05 Sep 2020' reason for change: Data Entry Error	Marla Schwarber (b) (4)	11 Sep 2020 20:31:07
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	11 Sep 2020 20:28:21
User entered '04 Sep 2020' reason for change: Data Entry Error	Marla Schwarber (b) (4)	11 Sep 2020 20:28:21
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	05 Sep 2020 15:00:12
User entered '05 Sep 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Sep 2020 15:00:12
User entered '04 Sep 2020' reason for change: Data Entry Error	(b) (4) Andrea Wendrow (b) (4)	05 Sep 2020 14:34:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:28:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered '09:07' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Sep 2020 15:00:12
	(b) (4)	
User entered '9:30' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Sep 2020 14:34:13
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:28:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User entered '04 Sep 2020 09:07'	System	03 Mar 2021 19:52:01
User entered '05 Sep 2020 09:07'	System	11 Sep 2020 20:31:07
User entered '04 Sep 2020 09:07'	System	11 Sep 2020 20:28:21
User entered '05 Sep 2020 09:07'	System	05 Sep 2020 15:00:12
User entered '04 Sep 2020 9:30'	System	05 Sep 2020 14:34:13
User entered empty.	System	04 Sep 2020 16:28:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
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)	05 Oct 2020 12:43:49
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).	Michelle Agnoli (b) (4) (b) (4)	01 Oct 2020 20:21:57
Amendment Manager: 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	17 Sep 2020 00:28:18
User entered '35.2' C reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	05 Sep 2020 15:00:12
User entered '36.5' C reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	05 Sep 2020 14:34:13
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:28:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered 'Other (Other)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Sep 2020 14:34:13
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:28:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered 'EAR' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Sep 2020 14:34:13
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:28:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered '59' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Sep 2020 15:00:12
	(b) (4)	
User entered '64' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Sep 2020 14:34:13
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:28:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User entered 'bpm'	(b) (4), (b) (6)	05 Sep 2020 14:34:13
User entered empty.	System	04 Sep 2020 16:28:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered '14' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Sep 2020 15:00:12
	(b) (4)	
User entered '16' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Sep 2020 14:34:13
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:28:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User entered 'breaths/min'	System	05 Sep 2020 14:34:13
User entered empty.	System	04 Sep 2020 16:28:40

US3492061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered '91' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Sep 2020 15:00:12
	(b) (4)	
User entered '105' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Sep 2020 14:34:13
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:28:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User entered 'mmHg'	(b) (4), (b) (6)	05 Sep 2020 14:34:13
User entered empty.	System	04 Sep 2020 16:28:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 12:43:53
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Michelle Agnoli (b) (4) (b) (4)	01 Oct 2020 20:22:07
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:28:18
User entered '59' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	05 Sep 2020 15:00:12
User entered '71' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	05 Sep 2020 14:34:13
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:28:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User entered 'mmHg'	(b) (4), (b) (6)	05 Sep 2020 14:34:13
User entered empty.	System	04 Sep 2020 16:28:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:50:42

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 05:16:45
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' answered with 'Corrected' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	21 Sep 2020 17:39:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4) (b) (4)	21 Sep 2020 17:39:17
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 17:32:42
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:28:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:50:42

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4)	21 Sep 2020 17:39:17
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:28:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	04 Sep 2020 16:28:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	05 Sep 2020 14:32:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 14:32:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	05 Sep 2020 14:32:55
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 16:28:40
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:28:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:44
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	03 Mar 2021 19:52:01
Signature has been broken.	Gizelle Alvarez (b) (4)	03 Mar 2021 19:52:01
User entered '04 Sep 2020' reason for change: Per Query Resolution	(b) (4) Gizelle Alvarez (b) (4)	03 Mar 2021 19:52:01
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	03 Mar 2021 19:51:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	19 Oct 2020 19:55:50
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Oct 2020 18:52:12
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Oct 2020 18:50:10
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	11 Sep 2020 20:31:52
User entered '05 Sep 2020' reason for change: Data Entry Error	Marla Schwarber (b) (4)	11 Sep 2020 20:31:52
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	11 Sep 2020 20:28:44
User entered '04 Sep 2020' reason for change: Data Entry Error	Marla Schwarber (b) (4)	11 Sep 2020 20:28:44
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	05 Sep 2020 15:00:24
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	05 Sep 2020 15:00:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '05 Sep 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Sep 2020 15:00:24
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	05 Sep 2020 14:32:55
User entered '5 Sep 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Sep 2020 14:32:55
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:28:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User closed query 'Per CDM: Pre-dose time of assessment is recorded at 09:07 and Post-dose time of assessment is recorded as 09:30. Per protocol, a minimum of 30 minutes is required between assessments. Please review and reconcile, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 08:42:49
Query 'Per CDM: Pre-dose time of assessment is recorded at 09:07 and Post-dose time of assessment is recorded as 09:30. Per protocol, a minimum of 30 minutes is required between assessments. Please review and reconcile, else clarify. ' answered with 'PD created' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	13 Oct 2020 19:00:43
User opened query 'Per CDM: Pre-dose time of assessment is recorded at 09:07 and Post-dose time of assessment is recorded as 09:30. Per protocol, a minimum of 30 minutes is required between assessments. Please review and reconcile, else clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 12:54:34
User closed query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	11 Sep 2020 20:31:52
User opened query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	11 Sep 2020 20:31:07
User entered '9:30' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	05 Sep 2020 14:32:55
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:28:40

US3492061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User entered '04 Sep 2020 9:30'	System	03 Mar 2021 19:52:01
User entered '05 Sep 2020 9:30'	System	11 Sep 2020 20:31:52
User entered '04 Sep 2020 9:30'	System	11 Sep 2020 20:28:44
User entered '05 Sep 2020 9:30'	System	05 Sep 2020 15:00:24
User entered '5 Sep 2020 9:30'	System	05 Sep 2020 14:32:55
User entered empty.	System	04 Sep 2020 16:28:40

US3492061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
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)	05 Oct 2020 12:44:14
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).	Michelle Agnoli (b) (4) (b) (4)	01 Oct 2020 20:24:38
Amendment Manager: 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	17 Sep 2020 00:28:18
User entered '35.2' C reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	05 Sep 2020 14:32:55
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:28:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered 'Other (Other)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Sep 2020 14:32:55
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:28:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered 'EAR' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Sep 2020 14:32:55
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:28:40

US3492061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered '62' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Sep 2020 14:32:55
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:28:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User entered 'bpm'	(b) (4), (b) (6)	05 Sep 2020 14:32:55
User entered empty.	System	04 Sep 2020 16:28:40

US3492061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered '16' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Sep 2020 14:32:55
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:28:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User entered 'breaths/min'	(b) (4), (b) (6)	05 Sep 2020 14:32:55
User entered empty.	System	04 Sep 2020 16:28:40

US3492061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered '104' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Sep 2020 14:32:55
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:28:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User entered 'mmHg'	(b) (4), (b) (6)	05 Sep 2020 14:32:55
User entered empty.	System	04 Sep 2020 16:28:40

US3492061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered '67' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Sep 2020 14:32:55
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:28:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User entered 'mmHg'	(b) (4), (b) (6)	05 Sep 2020 14:32:55
User entered empty.	System	04 Sep 2020 16:28:40

US3492061

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:50:42

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User closed query 'Per CDM: As a physical examination is recorded on Screening page, please update to NO per CCGs pg 15-16, and remove pregnancy test data from this page.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:25:33
Query 'Per CDM: As a physical examination is recorded on Screening page, please update to NO per CCGs pg 15-16, and remove pregnancy test data from this page.' answered with 'updated' (Site from DM).	Lorna Sanchez McCann (b) (4)	08 Oct 2020 16:05:37
User entered 'No (N)' reason for change: Per Query Resolution	Lorna Sanchez McCann (b) (4)	08 Oct 2020 16:05:16
User opened query 'Per CDM: As a physical examination is recorded on Screening page, please update to NO per CCGs pg 15-16, and remove pregnancy test data from this page.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 12:12:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 16:36:13

US3492061

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:50:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	08 Oct 2020 16:05:30
User entered empty; reason for change Per Query Resolution	Lorna Sanchez McCann (b) (4)	08 Oct 2020 16:05:30
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Oct 2020 16:05:16
User entered ' Sep ' (non-conformant).	Lorna Sanchez McCann	08 Oct 2020 16:05:16
User entered '4 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:36:13

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:50:42

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User closed query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:11:44
User entered 'No (N)' reason for change: Data Entry Error	Nusirat Williams (b) (4) (b) (4)	07 Oct 2020 15:12:50
Query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' answered with 'corrected' (Site from DM).	Nusirat Williams (b) (4) (b) (4)	07 Oct 2020 15:12:39
User opened query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 12:47:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 16:32:51

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:50:42

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	07 Oct 2020 15:12:50
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 15:12:42
User entered empty; reason for change Data Entry Error	Nusirat Williams (b) (4) (b) (4)	07 Oct 2020 15:12:42
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 16:32:51

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:50:42

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 15:12:50
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 15:12:42
User entered empty; reason for change Data Entry Error	Nusirat Williams (b) (4)	07 Oct 2020 15:12:42
	(b) (4)	
User entered 'Urine (URINE)'	(b) (4), (b) (6)	04 Sep 2020 16:32:51

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:50:42

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 15:12:50
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 15:12:42
User entered empty; reason for change Data Entry Error	Nusirat Williams (b) (4)	07 Oct 2020 15:12:42
	(b) (4)	
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	04 Sep 2020 16:32:51

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:50:42

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User closed query 'Per CDM: A yes/no response it required for this field. Please update. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:51:18
Query 'Per CDM: A yes/no response it required for this field. Please update. ' answered with 'updated' (Site from DM).	Lorna Sanchez McCann (b) (4)	08 Oct 2020 16:06:10
User entered 'No (N)' reason for change: Data Entry Error	Lorna Sanchez McCann (b) (4)	08 Oct 2020 16:06:01
User opened query 'Per CDM: A yes/no response it required for this field. Please update. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 12:11:48
User entered empty; reason for change Data Entry Error	Nusirat Williams (b) (4) (b) (4)	07 Oct 2020 15:12:42
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 16:32:51

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:50:42

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:32:51

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:50:42

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:32:51

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User entered empty.	(b) (4), (b) (6) System	04 Sep 2020 16:32:51

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:50:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	(b) (4) System	05 Sep 2020 14:28:56
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	05 Sep 2020 14:28:56
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	05 Sep 2020 14:28:00
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	05 Sep 2020 14:28:00

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:50:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	05 Sep 2020 14:28:00
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	05 Sep 2020 14:28:00

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:50:42

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	05 Sep 2020 14:28:00

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:50:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:44
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	03 Mar 2021 19:53:31
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	03 Mar 2021 19:53:31
Signature has been broken.	Gizelle Alvarez (b) (4)	03 Mar 2021 19:53:31
User entered '4 Sep 2020' reason for change: Per Query Resolution	(b) (4) Gizelle Alvarez (b) (4)	03 Mar 2021 19:53:31
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	03 Mar 2021 19:51:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	19 Oct 2020 19:55:50
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	19 Oct 2020 19:55:50
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	13 Oct 2020 18:52:12
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 15:01:36
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered with 'Subject screened 04Sep2020, began activities for Visit 1 Day 1 on 04Sep2020, was randomized and prior to receiving dose had to leave for work related activity that could not be rescheduled. Came back on 05Sep2020 to receive injection and complete Visit 1 day 1' (Site from System).	Andrea Wendrow (b) (4)	05 Sep 2020 15:07:47
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	05 Sep 2020 14:28:00

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:50:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '5 Sep 2020'	Andrea Wendrow (b) (4)	05 Sep 2020 14:28:00
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered '09:22' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Sep 2020 14:28:56
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	05 Sep 2020 14:28:00
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User entered '4 Sep 2020 09:22'	System	03 Mar 2021 19:53:31
User entered '5 Sep 2020 09:22'	System	05 Sep 2020 14:28:56
User entered empty.	System	05 Sep 2020 14:28:00

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Nusirat Williams (b) (4)	05 Oct 2020 21:19:43
	(b) (4)	
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	Nusirat Williams (b) (4)	05 Oct 2020 21:19:25
	(b) (4)	
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	05 Sep 2020 14:28:56
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	05 Sep 2020 14:28:00
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User entered 'ONCE'	(b) (4), (b) (6) System	05 Sep 2020 14:28:00

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:50:42

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	05 Sep 2020 14:28:00

US3492061

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:50:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 16:34:50

US3492061

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:50:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:44
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	03 Mar 2021 19:53:57
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		03 Mar 2021 19:53:57
User entered '04 Sep 2020' reason for change: Per Query Resolution	Gizelle Alvarez (b) (4) (b) (4)	03 Mar 2021 19:53:57
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	03 Mar 2021 19:51:41
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	03 Mar 2021 19:49:47
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		03 Mar 2021 19:49:47
Signature has been broken.	Gizelle Alvarez (b) (4) (b) (4)	03 Mar 2021 19:49:47
User entered '05 Sep 2020' reason for change: Per Query Resolution	Gizelle Alvarez (b) (4) (b) (4)	03 Mar 2021 19:49:47
Amendment Manager: User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Feb 2021 00:19:28
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:35:51
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 11:47:49
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' answered with 'Subject completed all study elements up to and including randomization on 04Sep2020. Realized had to leave prior to injection for unavoidable work appointment. Returned next day for injection and rest of Day 1 visit.' (Site from System).	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 20:05:36

US3492061

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:50:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Oct 2020 19:55:50
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Oct 2020 18:52:12
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		13 Oct 2020 18:52:12
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Oct 2020 18:50:10
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 16:34:50

US3492061

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered '10:20'	(b) (4), (b) (6)	04 Sep 2020 16:34:50

US3492061

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User entered '04 Sep 2020 10:20'	System	03 Mar 2021 19:53:57
User entered '05 Sep 2020 10:20'	System	03 Mar 2021 19:49:47
User entered '4 Sep 2020 10:20'	System	04 Sep 2020 16:34:50

US3492061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:50:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 13:34:36
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' answered with 'Subject completed all study elements up to and including randomization on 04Sep2020. Realized had to leave prior to injection for unavoidable work appointment. Returned next day for injection and rest of Day 1 visit.' (Site from System).	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 20:05:22
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Oct 2020 19:55:50
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Oct 2020 18:52:12
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	13 Oct 2020 18:52:12
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Oct 2020 18:50:10
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 16:35:50

US3492061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:50:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) (b) (4), (b) (6)	04 Sep 2020 16:35:50

US3492061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:50:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:35:50

US3492061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:50:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '10:30'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:35:50

US3492061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User entered '4 Sep 2020 10:30'	(b) (4), (b) (6) System	04 Sep 2020 16:35:50

US3492061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:50:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) (b) (4), (b) (6)	04 Sep 2020 16:35:50

US3492061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:50:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:35:50

US3492061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:35:50

US3492061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User entered empty.	(b) (4), (b) (6) System	04 Sep 2020 16:35:50

US3492061

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	05 Sep 2020 14:34:55
	(b) (4)	

US3492061

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User entered 'I'	(b) (4), (b) (6) System	05 Sep 2020 14:34:55

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
Data entry locked.	System	05 Sep 2020 14:28:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T09:42:19', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '0f34af2d-61f4-4823-9c00-64e0a6997250' User entered 'Yes (Y)'	(b) (4), (b) (6) System	05 Sep 2020 14:44:07
	System	05 Sep 2020 14:44:07

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T09:42:49', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '0f34af2d-61f4-4823-9c00-64e0a6997250' User entered '95.4'	(b) (4), (b) (6) System	05 Sep 2020 14:44:07
	System	05 Sep 2020 14:44:07

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T09:43:19', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '0f34af2d-61f4-4823-9c00-64e0a6997250'	(b) (4), (b) (6)	05 Sep 2020 14:44:07
User entered 'Yes (Y)'	System	05 Sep 2020 14:44:07

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T09:43:25', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '0f34af2d-61f4-4823-9c00-64e0a6997250' User entered '0'	(b) (4), (b) (6) System	05 Sep 2020 14:44:07
	System	05 Sep 2020 14:44:07

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reported taking 600mg dose of ibuprofen in am prior to study visit for a headache. This was taken prior to study injection' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	07 Sep 2020 15:02:23
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T09:43:25', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '0f34af2d-61f4-4823-9c00-64e0a6997250' User entered '1'	Andrea Wendrow (b) (4) (b) (4)	05 Sep 2020 15:03:06
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	05 Sep 2020 14:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T09:43:25', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '0f34af2d-61f4-4823-9c00-64e0a6997250' User entered '1'	System	05 Sep 2020 14:44:07
User entered '1'	System	05 Sep 2020 14:44:07

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T09:44:05', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '0f34af2d-61f4-4823-9c00-64e0a6997250' User entered '05 Sep 2020 09:44'	(b) (4), (b) (6) System	05 Sep 2020 14:44:07
	System	05 Sep 2020 14:44:07

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '05 Sep 2020 09:42'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '05 Sep 2020 12:12'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Sep 2020 14:28:56
User entered 'Day 1, after vaccination (at home)'	System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T23:43:08', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '315fc753-3a30-4249-9be8-4f6480c3a369' User entered 'Yes (Y)'	(b) (4), (b) (6) System	06 Sep 2020 04:43:27
	System	06 Sep 2020 04:43:27

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T23:43:13', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '315fc753-3a30-4249-9be8-4f6480c3a369' User entered '96.2'	(b) (4), (b) (6) System	06 Sep 2020 04:43:27
	System	06 Sep 2020 04:43:27

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T23:43:17', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '315fc753-3a30-4249-9be8-4f6480c3a369'	(b) (4), (b) (6)	06 Sep 2020 04:43:27
User entered 'Yes (Y)'	System	06 Sep 2020 04:43:27

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Took a medication for a headache that started prior to the injection' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	14 Sep 2020 10:36:04
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Addis Mekonnen (b) (4) (b) (4)	11 Sep 2020 17:26:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T23:43:19', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '315fc753-3a30-4249-9be8-4f6480c3a369'	System	06 Sep 2020 04:43:27
User entered '1'	System	06 Sep 2020 04:43:27

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T23:43:19', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '315fc753-3a30-4249-9be8-4f6480c3a369' User entered '0'	(b) (4), (b) (6) System	06 Sep 2020 04:43:27
	System	06 Sep 2020 04:43:27

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T23:43:25', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '315fc753-3a30-4249-9be8-4f6480c3a369' User entered '05 Sep 2020 23:43'	(b) (4), (b) (6) System	06 Sep 2020 04:43:27
	System	06 Sep 2020 04:43:27

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '05 Sep 2020 13:07'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '06 Sep 2020 11:59'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Sep 2020 14:28:56
User entered 'Day 2'	System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:50:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-06T21:26:01', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'fba39326-becc-49fb-9cf3-a7560c381dee' User entered 'Yes (Y)'	(b) (4), (b) (6) System	07 Sep 2020 02:26:14
	System	07 Sep 2020 02:26:14

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:50:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-06T21:26:04', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'fba39326-becc-49fb-9cf3-a7560c381dee' User entered '97.4'	(b) (4), (b) (6) System	07 Sep 2020 02:26:14
	System	07 Sep 2020 02:26:14

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-06T21:26:10', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'fba39326-becc-49fb-9cf3-a7560c381dee' User entered 'No (N)'	(b) (4), (b) (6) System	07 Sep 2020 02:26:14
	System	07 Sep 2020 02:26:14

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-06T21:26:12', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'fba39326-becc-49fb-9cf3-a7560c381dee' User entered '06 Sep 2020 21:26'	(b) (4), (b) (6) System	07 Sep 2020 02:26:14
	System	07 Sep 2020 02:26:14

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '06 Sep 2020 12:00'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '07 Sep 2020 11:59'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Sep 2020 14:28:56
User entered 'Day 3'	System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:50:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-07T22:11:12', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '81d4f416-40a5-4375-8c7b-79ac9fd654e5' User entered 'Yes (Y)'	(b) (4), (b) (6) System	08 Sep 2020 03:11:24
	System	08 Sep 2020 03:11:24

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:50:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-07T22:11:17', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '81d4f416-40a5-4375-8c7b-79ac9fd654e5' User entered '96.8'	(b) (4), (b) (6) System	08 Sep 2020 03:11:24
	System	08 Sep 2020 03:11:24

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-07T22:11:19', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '81d4f416-40a5-4375-8c7b-79ac9fd654e5' User entered 'No (N)'	(b) (4), (b) (6) System	08 Sep 2020 03:11:24
	System	08 Sep 2020 03:11:24

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-07T22:11:23', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '81d4f416-40a5-4375-8c7b-79ac9fd654e5' User entered '07 Sep 2020 22:11'	(b) (4), (b) (6) System	08 Sep 2020 03:11:24
	System	08 Sep 2020 03:11:24

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '07 Sep 2020 12:00'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '08 Sep 2020 11:59'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Sep 2020 14:28:56
User entered 'Day 4'	System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:50:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-08T22:18:49', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '674a3796-fc63-424a-8863-e0a8fea305bd' User entered 'Yes (Y)'	(b) (4), (b) (6) System	09 Sep 2020 03:19:03
	System	09 Sep 2020 03:19:03

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:50:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-08T22:18:53', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '674a3796-fc63-424a-8863-e0a8fea305bd' User entered '97.5'	(b) (4), (b) (6) System	09 Sep 2020 03:19:03
	System	09 Sep 2020 03:19:03

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-08T22:18:57', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '674a3796-fc63-424a-8863-e0a8fea305bd' User entered 'No (N)'	(b) (4), (b) (6) System	09 Sep 2020 03:19:03
	System	09 Sep 2020 03:19:03

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-08T22:18:59', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '674a3796-fc63-424a-8863-e0a8fea305bd' User entered '08 Sep 2020 22:18'	(b) (4), (b) (6) System	09 Sep 2020 03:19:03
	System	09 Sep 2020 03:19:03

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '08 Sep 2020 12:00'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '09 Sep 2020 11:59'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Sep 2020 14:28:56
User entered 'Day 5'	System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:50:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-09T22:19:01', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '27c7df64-dc38-4a42-afa0-8bfa37bff2ef' User entered 'Yes (Y)'	(b) (4), (b) (6) System	10 Sep 2020 03:19:20
	System	10 Sep 2020 03:19:20

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:50:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-09T22:19:11', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '27c7df64-dc38-4a42-afa0-8bfa37bff2ef' User entered '96.9'	(b) (4), (b) (6) System	10 Sep 2020 03:19:20
	System	10 Sep 2020 03:19:20

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-09T22:19:14', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '27c7df64-dc38-4a42-afa0-8bfa37bff2ef' User entered 'No (N)'	(b) (4), (b) (6) System	10 Sep 2020 03:19:20
	System	10 Sep 2020 03:19:20

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-09T22:19:16', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '27c7df64-dc38-4a42-afa0-8bfa37bff2ef' User entered '09 Sep 2020 22:19'	(b) (4), (b) (6) System	10 Sep 2020 03:19:20
	System	10 Sep 2020 03:19:20

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '09 Sep 2020 12:00'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '10 Sep 2020 11:59'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Sep 2020 14:28:56
User entered 'Day 6'	System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:50:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-10T22:49:16', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '53e7ba5c-a4d5-4cd0-9df4-104fe900547e' User entered 'Yes (Y)'	(b) (4), (b) (6) System	11 Sep 2020 03:49:27
	System	11 Sep 2020 03:49:27

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:50:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-10T22:49:21', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '53e7ba5c-a4d5-4cd0-9df4-104fe900547e' User entered '97.9'	(b) (4), (b) (6) System	11 Sep 2020 03:49:27
	System	11 Sep 2020 03:49:27

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-10T22:49:23', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '53e7ba5c-a4d5-4cd0-9df4-104fe900547e' User entered 'No (N)'	(b) (4), (b) (6) System	11 Sep 2020 03:49:27
	System	11 Sep 2020 03:49:27

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-10T22:49:25', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '53e7ba5c-a4d5-4cd0-9df4-104fe900547e' User entered '10 Sep 2020 22:49'	(b) (4), (b) (6) System	11 Sep 2020 03:49:27
	System	11 Sep 2020 03:49:27

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '10 Sep 2020 12:00'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '11 Sep 2020 11:59'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Sep 2020 14:28:56
User entered 'Day 7'	System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:50:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-11T21:27:29', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'e07523c9-74cf-4f98-ac4d-fc74ce85b68f' User entered 'Yes (Y)'	(b) (4), (b) (6) System	12 Sep 2020 02:28:11
	System	12 Sep 2020 02:28:11

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:50:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-11T21:27:32', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'e07523c9-74cf-4f98-ac4d-fc74ce85b68f' User entered '97.2'	(b) (4), (b) (6) System	12 Sep 2020 02:28:11
	System	12 Sep 2020 02:28:11

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-11T21:27:37', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'e07523c9-74cf-4f98-ac4d-fc74ce85b68f' User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 02:28:11
	System	12 Sep 2020 02:28:11

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-11T21:27:39', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'e07523c9-74cf-4f98-ac4d-fc74ce85b68f' User entered '11 Sep 2020 21:27'	(b) (4), (b) (6) System	12 Sep 2020 02:28:11
	System	12 Sep 2020 02:28:11

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '11 Sep 2020 12:00'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Sep 2020 14:28:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T09:44:09', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'dd3f3a3e-bacf-4692-b5f9-04a2ff21f042'	(b) (4), (b) (6) System	05 Sep 2020 14:45:15
User entered 'None (1)'	System	05 Sep 2020 14:45:15

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T09:44:44', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'dd3f3a3e-bacf-4692-b5f9-04a2ff21f042'	(b) (4), (b) (6)	
	System	05 Sep 2020 14:45:15
User entered 'No (N)'	System	05 Sep 2020 14:45:15

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T09:44:47', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'dd3f3a3e-bacf-4692-b5f9-04a2ff21f042'	(b) (4), (b) (6)	05 Sep 2020 14:45:15
User entered 'No (N)'	System	05 Sep 2020 14:45:15

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T09:44:50', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'dd3f3a3e-bacf-4692-b5f9-04a2ff21f042'	(b) (4), (b) (6)	05 Sep 2020 14:45:15
User entered 'None (1)'	System	05 Sep 2020 14:45:15

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T09:45:14', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'dd3f3a3e-bacf-4692-b5f9-04a2ff21f042'	(b) (4), (b) (6) System	05 Sep 2020 14:45:15
User entered '05 Sep 2020 09:45'	System	05 Sep 2020 14:45:15

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '05 Sep 2020 09:42'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '05 Sep 2020 12:12'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Sep 2020 14:28:56
User entered 'Day 1, after vaccination (at home)'	System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T23:43:38', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'aaa4ee3c-0961-4149-969e-6bec82462b5e'	(b) (4), (b) (6)	06 Sep 2020 04:43:48
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'	System	06 Sep 2020 04:43:48

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T23:43:39', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'aaa4ee3c-0961-4149-969e-6bec82462b5e' User entered 'No (N)'	(b) (4), (b) (6) System	06 Sep 2020 04:43:48
	System	06 Sep 2020 04:43:48

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T23:43:41', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'aaa4ee3c-0961-4149-969e-6bec82462b5e' User entered 'No (N)'	(b) (4), (b) (6) System	06 Sep 2020 04:43:48
	System	06 Sep 2020 04:43:48

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T23:43:43', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'aaa4ee3c-0961-4149-969e-6bec82462b5e' User entered 'None (1)'	(b) (4), (b) (6) System	06 Sep 2020 04:43:48
	System	06 Sep 2020 04:43:48

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T23:43:46', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'aaa4ee3c-0961-4149-969e-6bec82462b5e' User entered '05 Sep 2020 23:43'	(b) (4), (b) (6) System	06 Sep 2020 04:43:48
	System	06 Sep 2020 04:43:48

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '05 Sep 2020 13:07'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '06 Sep 2020 11:59'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Sep 2020 14:28:56
User entered 'Day 2'	System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-06T21:26:17', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '57796e88-f12a-439f-a344-bfffc980ee05'	(b) (4), (b) (6)	07 Sep 2020 02:26:30
User entered 'Does not interfere with activity (2)'	System	07 Sep 2020 02:26:30

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:50:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-06T21:26:19', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '57796e88-f12a-439f-a344-bfffc980ee05' User entered 'No (N)'	(b) (4), (b) (6) System	07 Sep 2020 02:26:30
	System	07 Sep 2020 02:26:30

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-06T21:26:23', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '57796e88-f12a-439f-a344-bfffc980ee05' User entered 'No (N)'	(b) (4), (b) (6) System	07 Sep 2020 02:26:30
	System	07 Sep 2020 02:26:30

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-06T21:26:25', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '57796e88-f12a-439f-a344-bfffc980ee05'	(b) (4), (b) (6)	07 Sep 2020 02:26:30
User entered 'None (1)'	System	07 Sep 2020 02:26:30

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-06T21:26:27', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '57796e88-f12a-439f-a344-bffc980ee05' User entered '06 Sep 2020 21:26'	(b) (4), (b) (6) System	07 Sep 2020 02:26:30
	System	07 Sep 2020 02:26:30

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '06 Sep 2020 12:00'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '07 Sep 2020 11:59'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Sep 2020 14:28:56
User entered 'Day 3'	System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-07T22:11:26', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'c32e16a7-737b-4897-8c49-d9e497eb3686' User entered 'None (1)'	(b) (4), (b) (6) System	08 Sep 2020 03:11:39
	System	08 Sep 2020 03:11:39

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:50:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-07T22:11:28', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'c32e16a7-737b-4897-8c49-d9e497eb3686' User entered 'No (N)'	(b) (4), (b) (6) System	08 Sep 2020 03:11:39
	System	08 Sep 2020 03:11:39

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-07T22:11:30', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'c32e16a7-737b-4897-8c49-d9e497eb3686' User entered 'No (N)'	(b) (4), (b) (6) System	08 Sep 2020 03:11:39
	System	08 Sep 2020 03:11:39

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-07T22:11:32', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'c32e16a7-737b-4897-8c49-d9e497eb3686' User entered 'None (1)'	(b) (4), (b) (6) System	08 Sep 2020 03:11:39
	System	08 Sep 2020 03:11:39

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-07T22:11:34', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'c32e16a7-737b-4897-8c49-d9e497eb3686' User entered '07 Sep 2020 22:11'	(b) (4), (b) (6) System	08 Sep 2020 03:11:39
	System	08 Sep 2020 03:11:39

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '07 Sep 2020 12:00'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '08 Sep 2020 11:59'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Sep 2020 14:28:56
User entered 'Day 4'	System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-08T22:18:06', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'cb5aef38-e3e9-4bfa-b68e-e568040fe140' User entered 'None (1)'	(b) (4), (b) (6) System	09 Sep 2020 03:18:14
	System	09 Sep 2020 03:18:14

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:50:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-08T22:18:07', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'cb5aef38-e3e9-4bfa-b68e-e568040fe140' User entered 'No (N)'	(b) (4), (b) (6) System	09 Sep 2020 03:18:14
	System	09 Sep 2020 03:18:14

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-08T22:18:08', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'cb5aef38-e3e9-4bfa-b68e-e568040fe140' User entered 'No (N)'	(b) (4), (b) (6) System	09 Sep 2020 03:18:14
	System	09 Sep 2020 03:18:14

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-08T22:18:10', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'cb5aef38-e3e9-4bfa-b68e-e568040fe140' User entered 'None (1)'	(b) (4), (b) (6) System	09 Sep 2020 03:18:14
	System	09 Sep 2020 03:18:14

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-08T22:18:12', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'cb5aef38-e3e9-4bfa-b68e-e568040fe140' User entered '08 Sep 2020 22:18'	(b) (4), (b) (6) System	09 Sep 2020 03:18:14
	System	09 Sep 2020 03:18:14

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '08 Sep 2020 12:00'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '09 Sep 2020 11:59'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Sep 2020 14:28:56
User entered 'Day 5'	System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-09T22:18:44', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '116edd01-0179-4411-878a-9300154b6d05'	(b) (4), (b) (6) System	10 Sep 2020 03:18:57
User entered 'None (1)'	System	10 Sep 2020 03:18:57

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:50:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-09T22:18:46', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '116edd01-0179-4411-878a-9300154b6d05' User entered 'No (N)'	(b) (4), (b) (6) System	10 Sep 2020 03:18:57
	System	10 Sep 2020 03:18:57

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-09T22:18:49', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '116edd01-0179-4411-878a-9300154b6d05' User entered 'No (N)'	(b) (4), (b) (6) System	10 Sep 2020 03:18:57
	System	10 Sep 2020 03:18:57

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-09T22:18:50', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '116edd01-0179-4411-878a-9300154b6d05' User entered 'None (1)'	(b) (4), (b) (6) System	10 Sep 2020 03:18:57
	System	10 Sep 2020 03:18:57

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-09T22:18:54', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '116edd01-0179-4411-878a-9300154b6d05' User entered '09 Sep 2020 22:18'	(b) (4), (b) (6) System	10 Sep 2020 03:18:57
	System	10 Sep 2020 03:18:57

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '09 Sep 2020 12:00'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '10 Sep 2020 11:59'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Sep 2020 14:28:56
User entered 'Day 6'	System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-10T22:48:32', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '9531a6fd-40b0-40d0-8f70-9d4b75eb7f4f' User entered 'None (1)'	(b) (4), (b) (6) System	11 Sep 2020 03:48:41
	System	11 Sep 2020 03:48:41

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:50:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-10T22:48:34', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '9531a6fd-40b0-40d0-8f70-9d4b75eb7f4f' User entered 'No (N)'	(b) (4), (b) (6) System	11 Sep 2020 03:48:41
	System	11 Sep 2020 03:48:41

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-10T22:48:35', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '9531a6fd-40b0-40d0-8f70-9d4b75eb7f4f' User entered 'No (N)'	(b) (4), (b) (6) System	11 Sep 2020 03:48:41
	System	11 Sep 2020 03:48:41

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-10T22:48:37', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '9531a6fd-40b0-40d0-8f70-9d4b75eb7f4f' User entered 'None (1)'	(b) (4), (b) (6) System	11 Sep 2020 03:48:41
	System	11 Sep 2020 03:48:41

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-10T22:48:39', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '9531a6fd-40b0-40d0-8f70-9d4b75eb7f4f' User entered '10 Sep 2020 22:48'	(b) (4), (b) (6) System	11 Sep 2020 03:48:41
	System	11 Sep 2020 03:48:41

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '10 Sep 2020 12:00'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '11 Sep 2020 11:59'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Sep 2020 14:28:56
User entered 'Day 7'	System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-11T21:27:19', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '967003ce-ffbe-45c5-a996-a00d32ba778b' User entered 'None (1)'	(b) (4), (b) (6) System	12 Sep 2020 02:28:27
	System	12 Sep 2020 02:28:27

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:50:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-11T21:27:20', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '967003ce-ffbe-45c5-a996-a00d32ba778b' User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 02:28:27
	System	12 Sep 2020 02:28:27

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-11T21:27:21', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '967003ce-ffbe-45c5-a996-a00d32ba778b' User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 02:28:27
	System	12 Sep 2020 02:28:27

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-11T21:27:23', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '967003ce-ffbe-45c5-a996-a00d32ba778b' User entered 'None (1)'	(b) (4), (b) (6) System	12 Sep 2020 02:28:27
	System	12 Sep 2020 02:28:27

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-11T21:27:24', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '967003ce-ffbe-45c5-a996-a00d32ba778b' User entered '11 Sep 2020 21:27'	(b) (4), (b) (6) System	12 Sep 2020 02:28:27
	System	12 Sep 2020 02:28:27

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '11 Sep 2020 12:00'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Sep 2020 14:28:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T09:45:18', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'f145dfbf-6c75-492a-9852-98f875149c6b' User entered 'None (0)'	(b) (4), (b) (6) System	05 Sep 2020 14:45:46
	System	05 Sep 2020 14:45:46

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T09:45:22', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'f145dfbf-6c75-492a-9852-98f875149c6b' User entered 'None (0)'	(b) (4), (b) (6) System	05 Sep 2020 14:45:46
	System	05 Sep 2020 14:45:46

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T09:45:31', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'f145dfbf-6c75-492a-9852-98f875149c6b' User entered 'None (0)'	(b) (4), (b) (6) System	05 Sep 2020 14:45:46
	System	05 Sep 2020 14:45:46

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T09:45:33', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'f145dfbf-6c75-492a-9852-98f875149c6b' User entered 'None (0)'	(b) (4), (b) (6) System	05 Sep 2020 14:45:46
	System	05 Sep 2020 14:45:46

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T09:45:34', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'f145dfbf-6c75-492a-9852-98f875149c6b' User entered 'None (0)'	(b) (4), (b) (6) System	05 Sep 2020 14:45:46
	System	05 Sep 2020 14:45:46

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T09:45:35', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'f145dfbf-6c75-492a-9852-98f875149c6b' User entered 'None (0)'	(b) (4), (b) (6) System	05 Sep 2020 14:45:46
	System	05 Sep 2020 14:45:46

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T09:45:41', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'f145dfbf-6c75-492a-9852-98f875149c6b' User entered 'No (N)'	(b) (4), (b) (6) System	05 Sep 2020 14:45:46
	System	05 Sep 2020 14:45:46

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T09:45:44', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'f145dfbf-6c75-492a-9852-98f875149c6b' User entered '05 Sep 2020 09:45'	(b) (4), (b) (6) System	05 Sep 2020 14:45:46
	System	05 Sep 2020 14:45:46

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '05 Sep 2020 09:42'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '05 Sep 2020 12:12'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Sep 2020 14:28:56
User entered 'Day 1, after vaccination (at home)'	System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T23:43:49', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '160ee05a-6038-438c-b52f-619ba1f1334d' User entered 'None (0)'	(b) (4), (b) (6) System	06 Sep 2020 04:44:03
	System	06 Sep 2020 04:44:03

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T23:43:52', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '160ee05a-6038-438c-b52f-619ba1f1334d' User entered 'None (0)'	(b) (4), (b) (6) System	06 Sep 2020 04:44:03
	System	06 Sep 2020 04:44:03

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T23:43:54', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '160ee05a-6038-438c-b52f-619ba1f1334d' User entered 'None (0)'	(b) (4), (b) (6) System	06 Sep 2020 04:44:03
	System	06 Sep 2020 04:44:03

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T23:43:55', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '160ee05a-6038-438c-b52f-619ba1f1334d' User entered 'None (0)'	(b) (4), (b) (6) System	06 Sep 2020 04:44:03
	System	06 Sep 2020 04:44:03

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T23:43:57', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '160ee05a-6038-438c-b52f-619ba1f1334d' User entered 'None (0)'	(b) (4), (b) (6) System	06 Sep 2020 04:44:03
	System	06 Sep 2020 04:44:03

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T23:43:58', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '160ee05a-6038-438c-b52f-619ba1f1334d' User entered 'None (0)'	(b) (4), (b) (6) System	06 Sep 2020 04:44:03
	System	06 Sep 2020 04:44:03

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T23:44:00', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '160ee05a-6038-438c-b52f-619ba1f1334d' User entered 'No (N)'	(b) (4), (b) (6) System	06 Sep 2020 04:44:03
	System	06 Sep 2020 04:44:03

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-05T23:44:02', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '160ee05a-6038-438c-b52f-619ba1f1334d' User entered '05 Sep 2020 23:44'	(b) (4), (b) (6) System	06 Sep 2020 04:44:03
	System	06 Sep 2020 04:44:03

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '05 Sep 2020 13:07'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '06 Sep 2020 11:59'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Sep 2020 14:28:56
User entered 'Day 2'	System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:50:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-06T21:26:31', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '3334ac74-84ba-41d4-810b-45bde7653d6e' User entered 'None (0)'	(b) (4), (b) (6) System	07 Sep 2020 02:26:42
	System	07 Sep 2020 02:26:42

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:50:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-06T21:26:31', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '3334ac74-84ba-41d4-810b-45bde7653d6e' User entered 'None (0)'	(b) (4), (b) (6) System	07 Sep 2020 02:26:42
	System	07 Sep 2020 02:26:42

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:50:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-06T21:26:32', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '3334ac74-84ba-41d4-810b-45bde7653d6e' User entered 'None (0)'	(b) (4), (b) (6) System	07 Sep 2020 02:26:42
	System	07 Sep 2020 02:26:42

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:50:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-06T21:26:33', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '3334ac74-84ba-41d4-810b-45bde7653d6e' User entered 'None (0)'	(b) (4), (b) (6) System	07 Sep 2020 02:26:42
	System	07 Sep 2020 02:26:42

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:50:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-06T21:26:34', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '3334ac74-84ba-41d4-810b-45bde7653d6e' User entered 'None (0)'	(b) (4), (b) (6) System	07 Sep 2020 02:26:42
	System	07 Sep 2020 02:26:42

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:50:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-06T21:26:35', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '3334ac74-84ba-41d4-810b-45bde7653d6e' User entered 'None (0)'	(b) (4), (b) (6) System	07 Sep 2020 02:26:42
	System	07 Sep 2020 02:26:42

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-06T21:26:37', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '3334ac74-84ba-41d4-810b-45bde7653d6e' User entered 'No (N)'	(b) (4), (b) (6) System	07 Sep 2020 02:26:42
	System	07 Sep 2020 02:26:42

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:50:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-06T21:26:39', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '3334ac74-84ba-41d4-810b-45bde7653d6e' User entered '06 Sep 2020 21:26'	(b) (4), (b) (6) System	07 Sep 2020 02:26:42
	System	07 Sep 2020 02:26:42

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '06 Sep 2020 12:00'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '07 Sep 2020 11:59'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Sep 2020 14:28:56
User entered 'Day 3'	System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:50:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-07T22:11:37', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'df56afac-8dc3-4a24-89d0-a0f78782ad97' User entered 'None (0)'	(b) (4), (b) (6) System	08 Sep 2020 03:11:49
	System	08 Sep 2020 03:11:49

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:50:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-07T22:11:38', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'df56afac-8dc3-4a24-89d0-a0f78782ad97' User entered 'None (0)'	(b) (4), (b) (6) System	08 Sep 2020 03:11:49
	System	08 Sep 2020 03:11:49

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:50:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-07T22:11:39', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'df56afac-8dc3-4a24-89d0-a0f78782ad97' User entered 'None (0)'	(b) (4), (b) (6) System	08 Sep 2020 03:11:49
	System	08 Sep 2020 03:11:49

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:50:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-07T22:11:41', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'df56afac-8dc3-4a24-89d0-a0f78782ad97' User entered 'None (0)'	(b) (4), (b) (6) System	08 Sep 2020 03:11:49
	System	08 Sep 2020 03:11:49

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:50:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-07T22:11:42', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'df56afac-8dc3-4a24-89d0-a0f78782ad97' User entered 'None (0)'	(b) (4), (b) (6) System	08 Sep 2020 03:11:49
	System	08 Sep 2020 03:11:49

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:50:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-07T22:11:43', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'df56afac-8dc3-4a24-89d0-a0f78782ad97' User entered 'None (0)'	(b) (4), (b) (6) System	08 Sep 2020 03:11:49
	System	08 Sep 2020 03:11:49

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-07T22:11:45', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'df56afac-8dc3-4a24-89d0-a0f78782ad97' User entered 'No (N)'	(b) (4), (b) (6) System	08 Sep 2020 03:11:49
	System	08 Sep 2020 03:11:49

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:50:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-07T22:11:47', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'df56afac-8dc3-4a24-89d0-a0f78782ad97' User entered '07 Sep 2020 22:11'	(b) (4), (b) (6) System	08 Sep 2020 03:11:49
	System	08 Sep 2020 03:11:49

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '07 Sep 2020 12:00'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '08 Sep 2020 11:59'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Sep 2020 14:28:56
User entered 'Day 4'	System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:50:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-08T22:18:14', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '4e62cecb-5fd1-41b2-a370-50efcdbd8d8c' User entered 'None (0)'	(b) (4), (b) (6) System	09 Sep 2020 03:18:30
	System	09 Sep 2020 03:18:30

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:50:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-08T22:18:15', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '4e62cecb-5fd1-41b2-a370-50efcdbd8d8c' User entered 'None (0)'	(b) (4), (b) (6) System	09 Sep 2020 03:18:30
	System	09 Sep 2020 03:18:30

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:50:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-08T22:18:16', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '4e62cecb-5fd1-41b2-a370-50efcdbd8d8c' User entered 'None (0)'	(b) (4), (b) (6) System	09 Sep 2020 03:18:30
	System	09 Sep 2020 03:18:30

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:50:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-08T22:18:17', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '4e62cecb-5fd1-41b2-a370-50efcdbd8d8c' User entered 'None (0)'	(b) (4), (b) (6) System	09 Sep 2020 03:18:30
	System	09 Sep 2020 03:18:30

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:50:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-08T22:18:18', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '4e62cecb-5fd1-41b2-a370-50efcdbd8d8c' User entered 'None (0)'	(b) (4), (b) (6) System	09 Sep 2020 03:18:30
	System	09 Sep 2020 03:18:30

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:50:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-08T22:18:19', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '4e62cecb-5fd1-41b2-a370-50efcdbd8d8c' User entered 'None (0)'	(b) (4), (b) (6) System	09 Sep 2020 03:18:30
	System	09 Sep 2020 03:18:30

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-08T22:18:24', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '4e62cecb-5fd1-41b2-a370-50efcdbd8d8c' User entered 'No (N)'	(b) (4), (b) (6) System	09 Sep 2020 03:18:30
	System	09 Sep 2020 03:18:30

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:50:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-08T22:18:25', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '4e62cecb-5fd1-41b2-a370-50efcdbd8d8c' User entered '08 Sep 2020 22:18'	(b) (4), (b) (6) System	09 Sep 2020 03:18:30
	System	09 Sep 2020 03:18:30

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '08 Sep 2020 12:00'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '09 Sep 2020 11:59'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Sep 2020 14:28:56
User entered 'Day 5'	System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:50:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-09T22:18:33', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'ebfd3bae-70e4-40c8-ad55-9bbd9d8f13d3' User entered 'None (0)'	(b) (4), (b) (6) System	10 Sep 2020 03:18:47
	System	10 Sep 2020 03:18:47

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:50:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-09T22:18:34', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'ebfd3bae-70e4-40c8-ad55-9bbd9d8f13d3' User entered 'None (0)'	(b) (4), (b) (6) System	10 Sep 2020 03:18:47
	System	10 Sep 2020 03:18:47

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:50:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-09T22:18:35', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'ebfd3bae-70e4-40c8-ad55-9bbd9d8f13d3' User entered 'None (0)'	(b) (4), (b) (6) System	10 Sep 2020 03:18:47
	System	10 Sep 2020 03:18:47

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:50:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-09T22:18:36', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'ebfd3bae-70e4-40c8-ad55-9bbd9d8f13d3' User entered 'None (0)'	(b) (4), (b) (6) System	10 Sep 2020 03:18:47
	System	10 Sep 2020 03:18:47

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:50:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-09T22:18:38', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'ebfd3bae-70e4-40c8-ad55-9bbd9d8f13d3' User entered 'None (0)'	(b) (4), (b) (6) System	10 Sep 2020 03:18:47
	System	10 Sep 2020 03:18:47

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:50:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-09T22:18:39', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'ebfd3bae-70e4-40c8-ad55-9bbd9d8f13d3' User entered 'None (0)'	(b) (4), (b) (6) System	10 Sep 2020 03:18:47
	System	10 Sep 2020 03:18:47

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-09T22:18:40', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'ebfd3bae-70e4-40c8-ad55-9bbd9d8f13d3' User entered 'No (N)'	(b) (4), (b) (6) System	10 Sep 2020 03:18:47
	System	10 Sep 2020 03:18:47

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:50:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-09T22:18:42', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'ebfd3bae-70e4-40c8-ad55-9bbd9d8f13d3' User entered '09 Sep 2020 22:18'	(b) (4), (b) (6) System	10 Sep 2020 03:18:47
	System	10 Sep 2020 03:18:47

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '09 Sep 2020 12:00'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '10 Sep 2020 11:59'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Sep 2020 14:28:56
User entered 'Day 6'	System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:50:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-10T22:48:42', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'e9ffa9b9-5c81-4e42-81cf-cd11420f3f5e' User entered 'None (0)'	(b) (4), (b) (6) System	11 Sep 2020 03:48:59
	System	11 Sep 2020 03:48:59

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:50:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-10T22:48:43', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'e9ffa9b9-5c81-4e42-81cf-cd11420f3f5e' User entered 'None (0)'	(b) (4), (b) (6) System	11 Sep 2020 03:48:59
	System	11 Sep 2020 03:48:59

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:50:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-10T22:48:45', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'e9ffa9b9-5c81-4e42-81cf-cd11420f3f5e' User entered 'None (0)'	(b) (4), (b) (6) System	11 Sep 2020 03:48:59
	System	11 Sep 2020 03:48:59

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:50:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-10T22:48:46', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'e9ffa9b9-5c81-4e42-81cf-cd11420f3f5e' User entered 'None (0)'	(b) (4), (b) (6) System	11 Sep 2020 03:48:59
	System	11 Sep 2020 03:48:59

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:50:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-10T22:48:48', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'e9ffa9b9-5c81-4e42-81cf-cd11420f3f5e' User entered 'None (0)'	(b) (4), (b) (6) System	11 Sep 2020 03:48:59
	System	11 Sep 2020 03:48:59

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:50:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-10T22:48:49', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'e9ffa9b9-5c81-4e42-81cf-cd11420f3f5e' User entered 'None (0)'	(b) (4), (b) (6) System	11 Sep 2020 03:48:59
	System	11 Sep 2020 03:48:59

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-10T22:48:51', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'e9ffa9b9-5c81-4e42-81cf-cd11420f3f5e' User entered 'No (N)'	(b) (4), (b) (6) System	11 Sep 2020 03:48:59
	System	11 Sep 2020 03:48:59

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:50:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-10T22:48:54', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'e9ffa9b9-5c81-4e42-81cf-cd11420f3f5e' User entered '10 Sep 2020 22:48'	(b) (4), (b) (6) System	11 Sep 2020 03:48:59
	System	11 Sep 2020 03:48:59

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '10 Sep 2020 12:00'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '11 Sep 2020 11:59'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Sep 2020 14:28:56
User entered 'Day 7'	System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:50:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-11T21:27:42', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '0c198b7c-e210-48c0-91be-bb2e78ca9f83' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 02:28:41
	System	12 Sep 2020 02:28:41

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:50:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-11T21:27:43', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '0c198b7c-e210-48c0-91be-bb2e78ca9f83' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 02:28:41
	System	12 Sep 2020 02:28:41

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:50:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-11T21:27:44', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '0c198b7c-e210-48c0-91be-bb2e78ca9f83' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 02:28:41
	System	12 Sep 2020 02:28:41

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:50:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-11T21:27:45', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '0c198b7c-e210-48c0-91be-bb2e78ca9f83' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 02:28:41
	System	12 Sep 2020 02:28:41

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:50:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-11T21:27:46', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '0c198b7c-e210-48c0-91be-bb2e78ca9f83' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 02:28:41
	System	12 Sep 2020 02:28:41

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:50:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-11T21:27:47', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '0c198b7c-e210-48c0-91be-bb2e78ca9f83' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 02:28:41
	System	12 Sep 2020 02:28:41

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-11T21:27:49', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '0c198b7c-e210-48c0-91be-bb2e78ca9f83' User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 02:28:41
	System	12 Sep 2020 02:28:41

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:50:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-09-11T21:27:51', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '0c198b7c-e210-48c0-91be-bb2e78ca9f83' User entered '11 Sep 2020 21:27'	(b) (4), (b) (6) System	12 Sep 2020 02:28:41
	System	12 Sep 2020 02:28:41

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '11 Sep 2020 12:00'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	05 Sep 2020 14:28:56

US3492061

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'Yes (Y)'	Addis Mekonnen (b) (4)	11 Sep 2020 17:18:39
	(b) (4)	

US3492061

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Sep 2020 10:34:53
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'screening was on 09/04/20 so today is day 8.' (Site from System).	Addis Mekonnen (b) (4) (b) (4)	11 Sep 2020 17:30:17
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	11 Sep 2020 17:18:39
User entered '11 Sep 2020'	Addis Mekonnen (b) (4) (b) (4)	11 Sep 2020 17:18:39

US3492061

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Addis Mekonnen (b) (4)	11 Sep 2020 17:18:39

US3492061

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered empty.	(b) (4) Addis Mekonnen (b) (4)	11 Sep 2020 17:18:39

US3492061

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'Yes (Y)'	Addis Mekonnen (b) (4)	11 Sep 2020 17:30:32
	(b) (4)	

US3492061

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User entered 'I'	(b) (4), (b) (6) System	11 Sep 2020 17:30:32

US3492061

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'Yes (Y)'	Elena Llinas (b) (4)	25 Sep 2020 15:32:10
	(b) (4)	

US3492061

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 07:01:11
User entered '21 Sep 2020' reason for change: Data Entry Error	Elena Llinas (b) (4) (b) (4)	25 Sep 2020 15:39:04
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	Elena Llinas (b) (4) (b) (4)	25 Sep 2020 15:35:08
answered with 'left multiple messages. participants never called back. on 09/25/20 I was able to complete Safety Call day 22. Elena' (Site from System).		
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	25 Sep 2020 15:32:10
User entered '18 Sep 2020'	Elena Llinas (b) (4) (b) (4)	25 Sep 2020 15:32:10

US3492061

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Elena Llinas (b) (4)	25 Sep 2020 15:39:04
reason for change: Data Entry Error	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	Elena Llinas (b) (4)	25 Sep 2020 15:32:10
	(b) (4)	

US3492061

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '09/18/20 LEFT A MESSAGE. ELENA	(b) (4) Elena Llinas (b) (4)	25 Sep 2020 15:39:04
09/21/20 contact made' reason for change: Data Entry Error		
User closed query 'The Contact Status is 'CONTACT System NOT MADE'; however, Comments have not been provided.		25 Sep 2020 15:33:08
Please review and reconcile.' (Site from System).		
User entered '09/18/20 left a message. Elena	Elena Llinas (b) (4)	25 Sep 2020 15:33:08
09/21/20 Left a message. Elena	(b) (4)	
09/22/20 left a message. Elena' reason for change: Data Entry Error		
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	25 Sep 2020 15:32:10
Please review and reconcile.' (Site from System).		
User entered empty.	Elena Llinas (b) (4) (b) (4)	25 Sep 2020 15:32:10

US3492061

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'Yes (Y)'	Elena Llinas (b) (4)	25 Sep 2020 15:35:30
	(b) (4)	

US3492061

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User entered 'I'	(b) (4), (b) (6) System	25 Sep 2020 15:35:30

US3492061

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Yes (Y)'	(b) (4) Elena Llinas (b) (4) (b) (4)	25 Sep 2020 15:35:43

US3492061

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 06:43:06
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Safety call performed within the window of the protocol. ' (Site from System).	Elena Llinas (b) (4) (b) (4)	25 Sep 2020 15:36:42
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	25 Sep 2020 15:35:43
User entered '25 Sep 2020'	Elena Llinas (b) (4) (b) (4)	25 Sep 2020 15:35:43

US3492061

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elena Llinas (b) (4) (b) (4)	25 Sep 2020 15:35:43

US3492061

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered empty.	(b) (4) Elena Llinas (b) (4) (b) (4)	25 Sep 2020 15:35:43

US3492061

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'Yes (Y)'	Elena Llinas (b) (4)	25 Sep 2020 15:36:54
	(b) (4)	

US3492061

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User entered 'I'	(b) (4), (b) (6) System	25 Sep 2020 15:36:54

US3492061

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:50:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered 'Yes (Y)'	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	05 Oct 2020 20:37:42

US3492061

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered '5 Oct 2020'	Gizelle Alvarez (b) (4)	05 Oct 2020 20:37:42
	(b) (4)	

US3492061

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered 'Clinic (Clinic)'	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	05 Oct 2020 20:37:42

US3492061

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:50:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User entered 'VISIT2'	(b) (4), (b) (6) System	05 Oct 2020 20:37:42

US3492061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Gizelle Alvarez (b) (4)	05 Oct 2020 20:39:08
	(b) (4)	

US3492061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered 'Yes (Y)'	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	05 Oct 2020 20:39:08

US3492061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered '5 Oct 2020'	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	05 Oct 2020 20:39:08

US3492061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	05 Oct 2020 20:39:20
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Oct 2020 20:39:20
User entered '15:21' reason for change: Data Entry Error	Gizelle Alvarez (b) (4) (b) (4)	05 Oct 2020 20:39:20
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Oct 2020 20:39:08
User entered empty.	Gizelle Alvarez (b) (4) (b) (4)	05 Oct 2020 20:39:08

US3492061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User entered '5 Oct 2020 15:21'	(b) (4), (b) (6)	
	System	05 Oct 2020 20:39:20
User entered empty.	System	05 Oct 2020 20:39:08

US3492061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered '97.9' F	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	05 Oct 2020 20:39:08

US3492061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered 'Other (Other)'	Gizelle Alvarez (b) (4)	05 Oct 2020 20:39:08
	(b) (4)	

US3492061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered 'tympanic'	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	05 Oct 2020 20:39:08

US3492061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered '68'	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	05 Oct 2020 20:39:08

US3492061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User entered 'bpm'	(b) (4), (b) (6) System	05 Oct 2020 20:39:08

US3492061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered '16'	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	05 Oct 2020 20:39:08

US3492061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User entered 'breaths/min'	(b) (4), (b) (6) System	05 Oct 2020 20:39:08

US3492061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered '116'	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	05 Oct 2020 20:39:08

US3492061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User entered 'mmHg'	(b) (4), (b) (6) System	05 Oct 2020 20:39:08

US3492061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered '73'	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	05 Oct 2020 20:39:08

US3492061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:50:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User entered 'mmHg'	(b) (4), (b) (6) System	05 Oct 2020 20:39:08

US3492061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Gizelle Alvarez (b) (4) (b) (4)	05 Oct 2020 20:39:08

US3492061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Nusirat Williams (b) (4)	05 Oct 2020 21:28:57
	(b) (4)	
User entered 'No (N)'	Gizelle Alvarez (b) (4)	05 Oct 2020 20:39:08
	(b) (4)	

US3492061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered '5 Oct 2020' reason for change: Data Entry Error	Nusirat Williams (b) (4)	05 Oct 2020 21:28:57
	(b) (4)	
User entered empty.	Gizelle Alvarez (b) (4)	05 Oct 2020 20:39:08
	(b) (4)	

US3492061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered '16:28' reason for change: Data Entry Error	Nusirat Williams (b) (4)	05 Oct 2020 21:28:57
	(b) (4)	
User entered empty.	Gizelle Alvarez (b) (4)	05 Oct 2020 20:39:08
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User entered '5 Oct 2020 16:28'	(b) (4), (b) (6)	
	System	05 Oct 2020 21:28:57
User entered empty.	System	05 Oct 2020 20:39:08

US3492061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered '36.7' C reason for change: Data Entry Error	Nusirat Williams (b) (4)	05 Oct 2020 21:28:57
	(b) (4)	
User entered empty.	Gizelle Alvarez (b) (4)	05 Oct 2020 20:39:08
	(b) (4)	

US3492061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered 'Other (Other)' reason for change: Data Entry Error	Nusirat Williams (b) (4)	05 Oct 2020 21:28:57
	(b) (4)	
User entered empty.	Gizelle Alvarez (b) (4)	05 Oct 2020 20:39:08
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered 'tympanic' reason for change: Data Entry Error	Nusirat Williams (b) (4)	05 Oct 2020 21:28:57
	(b) (4)	
User entered empty.	Gizelle Alvarez (b) (4)	05 Oct 2020 20:39:08
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered '64' reason for change: Data Entry Error	Nusirat Williams (b) (4)	05 Oct 2020 21:28:57
	(b) (4)	
User entered empty.	Gizelle Alvarez (b) (4)	05 Oct 2020 20:39:08
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User entered 'bpm'	(b) (4), (b) (6)	05 Oct 2020 21:28:57
User entered empty.	System	05 Oct 2020 20:39:08

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered '18' reason for change: Data Entry Error	Nusirat Williams (b) (4)	05 Oct 2020 21:28:57
	(b) (4)	
User entered empty.	Gizelle Alvarez (b) (4)	05 Oct 2020 20:39:08
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
	(b) (4), (b) (6)	
User entered 'breaths/min'	System	05 Oct 2020 21:28:57
User entered empty.	System	05 Oct 2020 20:39:08

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered '116' reason for change: Data Entry Error	Nusirat Williams (b) (4)	05 Oct 2020 21:28:57
	(b) (4)	
User entered empty.	Gizelle Alvarez (b) (4)	05 Oct 2020 20:39:08
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User entered 'mmHg'	(b) (4), (b) (6)	
	System	05 Oct 2020 21:28:57
User entered empty.	System	05 Oct 2020 20:39:08

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered '77' reason for change: Data Entry Error	Nusirat Williams (b) (4)	05 Oct 2020 21:28:57
	(b) (4)	
User entered empty.	Gizelle Alvarez (b) (4)	05 Oct 2020 20:39:08
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:50:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User entered 'mmHg'	(b) (4), (b) (6)	05 Oct 2020 21:28:57
User entered empty.	System	05 Oct 2020 20:39:08

US3492061

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:50:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered 'Yes (Y)'	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	05 Oct 2020 20:39:28

US3492061

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:50:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered '5 Oct 2020'	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	05 Oct 2020 20:39:28

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Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:50:42

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	05 Oct 2020 20:40:25
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:50:42

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered '5 Oct 2020'	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	05 Oct 2020 20:40:25

US3492061

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:50:42

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered 'Urine (URINE)'	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	05 Oct 2020 20:40:25

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Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:50:42

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered 'Negative (NEGATIVE)'	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	05 Oct 2020 20:40:25

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Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:50:42

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered 'No (N)'	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	05 Oct 2020 20:40:25

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Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:50:42

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered empty.	Gizelle Alvarez (b) (4)	05 Oct 2020 20:40:25
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:50:42

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered empty.	Gizelle Alvarez (b) (4)	05 Oct 2020 20:40:25
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User entered empty.	(b) (4), (b) (6) System	05 Oct 2020 20:40:25

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:50:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	05 Oct 2020 21:18:33
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:50:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered empty.	Nusirat Williams (b) (4)	05 Oct 2020 21:18:33
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered empty.	(b) (4) Nusirat Williams (b) (4)	05 Oct 2020 21:18:33

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:50:42

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:50:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered '5 Oct 2020'	Nusirat Williams (b) (4)	05 Oct 2020 21:18:33
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered '16:20' reason for change: Data Entry Error	Nusirat Williams (b) (4)	05 Oct 2020 21:29:54
	(b) (4)	
User entered '16:13'	Nusirat Williams (b) (4)	05 Oct 2020 21:18:33
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
	(b) (4), (b) (6)	
User entered '5 Oct 2020 16:20'	System	05 Oct 2020 21:29:54
User entered '5 Oct 2020 16:13'	System	05 Oct 2020 21:18:33

US3492061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:50:42

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4) System	05 Oct 2020 21:29:14
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	05 Oct 2020 21:29:14
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Nusirat Williams (b) (4) (b) (4)	05 Oct 2020 21:29:14
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	05 Oct 2020 21:19:43
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	05 Oct 2020 21:19:25
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	05 Oct 2020 21:19:25
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	05 Oct 2020 21:18:33
User entered 'Right Arm (RIGHT ARM)'	Nusirat Williams (b) (4) (b) (4)	05 Oct 2020 21:18:33

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User entered 'ONCE'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:50:42

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

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Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:50:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered 'Yes (Y)'	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	05 Oct 2020 20:50:59

US3492061

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:50:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered '5 Oct 2020'	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	05 Oct 2020 20:50:59

US3492061

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:50:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered '15:40'	Gizelle Alvarez (b) (4)	05 Oct 2020 20:50:59
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User entered '5 Oct 2020 15:40'	(b) (4), (b) (6) System	05 Oct 2020 20:50:59

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:50:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered '5 Oct 2020'	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	05 Oct 2020 20:52:07

US3492061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:50:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) Gizelle Alvarez (b) (4) (b) (4)	05 Oct 2020 20:52:07

US3492061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:50:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	05 Oct 2020 20:52:07
	(b) (4)	

US3492061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered '15:50'	Gizelle Alvarez (b) (4)	05 Oct 2020 20:52:07
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User entered '5 Oct 2020 15:50'	(b) (4), (b) (6) System	05 Oct 2020 20:52:07

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:50:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Gizelle Alvarez (b) (4) (b) (4)	05 Oct 2020 20:52:07

US3492061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:50:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered 'No (N)'	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	05 Oct 2020 20:52:07

US3492061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered empty.	Gizelle Alvarez (b) (4)	05 Oct 2020 20:52:07
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User entered empty.	(b) (4), (b) (6) System	05 Oct 2020 20:52:07

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Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:57
	(b) (4)	
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	05 Oct 2020 20:40:49
	(b) (4)	

US3492061

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User entered 'I'	(b) (4), (b) (6) System	05 Oct 2020 20:40:49

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Oct 2020 21:18:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-05T19:05:21', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'abb3e23a-933e-4e77-afe7-ddab0ca0ee45' User entered 'No (N)'	(b) (4), (b) (6) System	06 Oct 2020 00:05:28
	System	06 Oct 2020 00:05:28

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-05T19:05:23', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'abb3e23a-933e-4e77-afe7-ddab0ca0ee45'	(b) (4), (b) (6)	06 Oct 2020 00:05:28
User entered 'No (N)'	System	06 Oct 2020 00:05:28

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-05T19:05:26', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'abb3e23a-933e-4e77-afe7-ddab0ca0ee45' User entered '05 Oct 2020 19:05'	(b) (4), (b) (6) System	06 Oct 2020 00:05:28
	System	06 Oct 2020 00:05:28

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
User entered '05 Oct 2020 16:40'	System	05 Oct 2020 21:29:54
User entered '05 Oct 2020 16:33'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
User entered '05 Oct 2020 19:10'	System	05 Oct 2020 21:29:54
User entered '05 Oct 2020 19:03'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Oct 2020 21:18:33
User entered 'Day 1, after vaccination (at home)'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:13:16

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:13:16

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:13:16

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:13:16

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:13:16

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:13:16

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
User entered '05 Oct 2020 20:05'	System	05 Oct 2020 21:29:54
User entered '05 Oct 2020 19:58'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '06 Oct 2020 11:59'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Oct 2020 21:18:33
User entered 'Day 2'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:50:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-06T20:07:14', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '87ead447-5092-45ee-baf4-177dd9ee19fc' User entered 'Yes (Y)'	(b) (4), (b) (6) System	07 Oct 2020 01:07:53
	System	07 Oct 2020 01:07:53

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:50:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-06T20:07:18', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '87ead447-5092-45ee-baf4-177dd9ee19fc' User entered '97.0'	(b) (4), (b) (6) System	07 Oct 2020 01:07:53
	System	07 Oct 2020 01:07:53

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-06T20:07:29', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '87ead447-5092-45ee-baf4-177dd9ee19fc'	(b) (4), (b) (6)	07 Oct 2020 01:07:53
User entered 'Yes (Y)'	System	07 Oct 2020 01:07:53

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'pain at injection site took ibuprofen' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 17:25:43
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 14:44:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-06T20:07:32', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '87ead447-5092-45ee-baf4-177dd9ee19fc'	System	07 Oct 2020 01:07:53
User entered '1'	System	07 Oct 2020 01:07:53

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:50:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-06T20:07:32', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '87ead447-5092-45ee-baf4-177dd9ee19fc' User entered '0'	(b) (4), (b) (6) System	07 Oct 2020 01:07:53
	System	07 Oct 2020 01:07:53

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-06T20:07:36', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '87ead447-5092-45ee-baf4-177dd9ee19fc' User entered '06 Oct 2020 20:07'	(b) (4), (b) (6) System	07 Oct 2020 01:07:53
	System	07 Oct 2020 01:07:53

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '06 Oct 2020 12:00'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '07 Oct 2020 11:59'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Oct 2020 21:18:33
User entered 'Day 3'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:50:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-07T22:41:30', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '64186ccb-bdc3-425b-9903-011ba8ffd0e4' User entered 'Yes (Y)'	(b) (4), (b) (6) System	08 Oct 2020 03:41:44
	System	08 Oct 2020 03:41:44

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:50:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-07T22:41:38', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '64186ccb-bdc3-425b-9903-011ba8ffd0e4' User entered '96.8'	(b) (4), (b) (6) System	08 Oct 2020 03:41:44
	System	08 Oct 2020 03:41:44

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-07T22:41:40', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '64186ccb-bdc3-425b-9903-011ba8ffd0e4' User entered 'No (N)'	(b) (4), (b) (6) System	08 Oct 2020 03:41:44
	System	08 Oct 2020 03:41:44

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-07T22:41:42', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '64186ccb-bdc3-425b-9903-011ba8ffd0e4' User entered '07 Oct 2020 22:41'	(b) (4), (b) (6) System	08 Oct 2020 03:41:44
	System	08 Oct 2020 03:41:44

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '07 Oct 2020 12:00'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '08 Oct 2020 11:59'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Oct 2020 21:18:33
User entered 'Day 4'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:50:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T09:43:53', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'a5e9918f-5ca5-4e06-ac74-2d07060a8aa7' User entered 'Yes (Y)'	(b) (4), (b) (6) System	09 Oct 2020 14:45:51
	System	09 Oct 2020 14:45:51

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:50:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T09:45:00', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'a5e9918f-5ca5-4e06-ac74-2d07060a8aa7' User entered '96.5'	(b) (4), (b) (6) System	09 Oct 2020 14:45:51
	System	09 Oct 2020 14:45:51

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T09:45:01', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'a5e9918f-5ca5-4e06-ac74-2d07060a8aa7' User entered 'No (N)'	(b) (4), (b) (6) System	09 Oct 2020 14:45:51
	System	09 Oct 2020 14:45:51

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T09:45:04', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'a5e9918f-5ca5-4e06-ac74-2d07060a8aa7' User entered '09 Oct 2020 09:45'	(b) (4), (b) (6) System	09 Oct 2020 14:45:51
	System	09 Oct 2020 14:45:51

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '08 Oct 2020 12:00'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '09 Oct 2020 11:59'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Oct 2020 21:18:33
User entered 'Day 5'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:50:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T20:00:14', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '76e9c678-0f0e-4b93-bfee-e531673d5b96' User entered 'Yes (Y)'	(b) (4), (b) (6) System	10 Oct 2020 01:00:28
	System	10 Oct 2020 01:00:28

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:50:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T20:00:19', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '76e9c678-0f0e-4b93-bfee-e531673d5b96' User entered '97.2'	(b) (4), (b) (6) System	10 Oct 2020 01:00:28
	System	10 Oct 2020 01:00:28

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T20:00:20', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '76e9c678-0f0e-4b93-bfee-e531673d5b96'	(b) (4), (b) (6)	10 Oct 2020 01:00:28
User entered 'No (N)'	System	10 Oct 2020 01:00:28

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T20:00:22', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '76e9c678-0f0e-4b93-bfee-e531673d5b96' User entered '09 Oct 2020 20:00'	(b) (4), (b) (6) System	10 Oct 2020 01:00:28
	System	10 Oct 2020 01:00:28

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '09 Oct 2020 12:00'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '10 Oct 2020 11:59'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Oct 2020 21:18:33
User entered 'Day 6'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:50:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-10T23:42:03', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '49316792-6112-4c6a-b822-c29f15c41613' User entered 'Yes (Y)'	(b) (4), (b) (6) System	11 Oct 2020 04:42:19
	System	11 Oct 2020 04:42:19

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:50:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-10T23:42:09', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '49316792-6112-4c6a-b822-c29f15c41613' User entered '97.4'	(b) (4), (b) (6) System	11 Oct 2020 04:42:19
	System	11 Oct 2020 04:42:19

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-10T23:42:13', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '49316792-6112-4c6a-b822-c29f15c41613' User entered 'No (N)'	(b) (4), (b) (6) System	11 Oct 2020 04:42:19
	System	11 Oct 2020 04:42:19

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-10T23:42:15', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '49316792-6112-4c6a-b822-c29f15c41613' User entered '10 Oct 2020 23:42'	(b) (4), (b) (6) System	11 Oct 2020 04:42:19
	System	11 Oct 2020 04:42:19

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '10 Oct 2020 12:00'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '11 Oct 2020 11:59'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Oct 2020 21:18:33
User entered 'Day 7'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:50:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-11T20:01:18', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'de8da94d-dc79-4c2f-ab1f-618d99b60b54' User entered 'Yes (Y)'	(b) (4), (b) (6) System	12 Oct 2020 01:01:39
	System	12 Oct 2020 01:01:39

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:50:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-11T20:01:27', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'de8da94d-dc79-4c2f-ab1f-618d99b60b54' User entered '98.2'	(b) (4), (b) (6) System	12 Oct 2020 01:01:39
	System	12 Oct 2020 01:01:39

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-11T20:01:30', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'de8da94d-dc79-4c2f-ab1f-618d99b60b54' User entered 'No (N)'	(b) (4), (b) (6) System	12 Oct 2020 01:01:39
	System	12 Oct 2020 01:01:39

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-11T20:01:32', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'de8da94d-dc79-4c2f-ab1f-618d99b60b54' User entered '11 Oct 2020 20:01'	(b) (4), (b) (6) System	12 Oct 2020 01:01:39
	System	12 Oct 2020 01:01:39

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '11 Oct 2020 12:00'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '12 Oct 2020 11:59'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Oct 2020 21:18:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-05T19:05:31', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'bb485c25-6772-40e2-8a7d-fa6eda49d425'	(b) (4), (b) (6)	06 Oct 2020 00:05:42
User entered 'Does not interfere with activity (2)'	System	06 Oct 2020 00:05:42

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-05T19:05:33', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'bb485c25-6772-40e2-8a7d-fa6eda49d425' User entered 'No (N)'	(b) (4), (b) (6) System	06 Oct 2020 00:05:42
	System	06 Oct 2020 00:05:42

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-05T19:05:35', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'bb485c25-6772-40e2-8a7d-fa6eda49d425' User entered 'No (N)'	(b) (4), (b) (6) System	06 Oct 2020 00:05:42
	System	06 Oct 2020 00:05:42

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-05T19:05:37', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'bb485c25-6772-40e2-8a7d-fa6eda49d425'	(b) (4), (b) (6)	06 Oct 2020 00:05:42
User entered 'None (1)'	System	06 Oct 2020 00:05:42

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-05T19:05:39', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'bb485c25-6772-40e2-8a7d-fa6eda49d425' User entered '05 Oct 2020 19:05'	(b) (4), (b) (6) System	06 Oct 2020 00:05:42
	System	06 Oct 2020 00:05:42

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
User entered '05 Oct 2020 16:40'	System	05 Oct 2020 21:29:54
User entered '05 Oct 2020 16:33'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
User entered '05 Oct 2020 19:10'	System	05 Oct 2020 21:29:54
User entered '05 Oct 2020 19:03'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Oct 2020 21:18:33
User entered 'Day 1, after vaccination (at home)'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:13:16

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:13:16

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:13:16

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:13:16

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
User entered '05 Oct 2020 20:05'	System	05 Oct 2020 21:29:54
User entered '05 Oct 2020 19:58'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '06 Oct 2020 11:59'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Oct 2020 21:18:33
User entered 'Day 2'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-06T20:07:50', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '34116d4a-3685-4097-a10d-b716a0d16f9a'	(b) (4), (b) (6)	07 Oct 2020 01:08:36
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'	System	07 Oct 2020 01:08:36

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:50:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-06T20:07:54', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '34116d4a-3685-4097-a10d-b716a0d16f9a' User entered 'No (N)'	(b) (4), (b) (6) System	07 Oct 2020 01:08:36
	System	07 Oct 2020 01:08:36

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-06T20:07:55', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '34116d4a-3685-4097-a10d-b716a0d16f9a' User entered 'No (N)'	(b) (4), (b) (6) System	07 Oct 2020 01:08:36
	System	07 Oct 2020 01:08:36

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-06T20:08:14', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '34116d4a-3685-4097-a10d-b716a0d16f9a' User entered 'None (1)'	(b) (4), (b) (6) System	07 Oct 2020 01:08:36
	System	07 Oct 2020 01:08:36

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-06T20:08:31', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '34116d4a-3685-4097-a10d-b716a0d16f9a' User entered '06 Oct 2020 20:08'	(b) (4), (b) (6) System	07 Oct 2020 01:08:36
	System	07 Oct 2020 01:08:36

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '06 Oct 2020 12:00'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '07 Oct 2020 11:59'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Oct 2020 21:18:33
User entered 'Day 3'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-07T22:41:46', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '384aa4cf-33c1-4c87-8b5a-ee0e90db2913'	(b) (4), (b) (6)	08 Oct 2020 03:41:56
User entered 'Does not interfere with activity (2)'	System	08 Oct 2020 03:41:56

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:50:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-07T22:41:49', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '384aa4cf-33c1-4c87-8b5a-ee0e90db2913' User entered 'No (N)'	(b) (4), (b) (6) System	08 Oct 2020 03:41:56
	System	08 Oct 2020 03:41:56

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-07T22:41:51', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '384aa4cf-33c1-4c87-8b5a-ee0e90db2913' User entered 'No (N)'	(b) (4), (b) (6) System	08 Oct 2020 03:41:56
	System	08 Oct 2020 03:41:56

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-07T22:41:53', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '384aa4cf-33c1-4c87-8b5a-ee0e90db2913' User entered 'None (1)'	(b) (4), (b) (6) System	08 Oct 2020 03:41:56
	System	08 Oct 2020 03:41:56

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-07T22:41:55', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '384aa4cf-33c1-4c87-8b5a-ee0e90db2913' User entered '07 Oct 2020 22:41'	(b) (4), (b) (6) System	08 Oct 2020 03:41:56
	System	08 Oct 2020 03:41:56

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '07 Oct 2020 12:00'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '08 Oct 2020 11:59'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Oct 2020 21:18:33
User entered 'Day 4'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T09:45:08', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '6f8037ae-f282-430c-8fb6-a3beee1c1f64'	(b) (4), (b) (6)	09 Oct 2020 14:45:51
User entered 'None (1)'	System	09 Oct 2020 14:45:51

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:50:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T09:45:10', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '6f8037ae-f282-430c-8fb6-a3beee1c1f64' User entered 'No (N)'	(b) (4), (b) (6) System	09 Oct 2020 14:45:51
	System	09 Oct 2020 14:45:51

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T09:45:11', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '6f8037ae-f282-430c-8fb6-a3beee1c1f64' User entered 'No (N)'	(b) (4), (b) (6) System	09 Oct 2020 14:45:51
	System	09 Oct 2020 14:45:51

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T09:45:12', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '6f8037ae-f282-430c-8fb6-a3beee1c1f64' User entered 'None (1)'	(b) (4), (b) (6) System	09 Oct 2020 14:45:51
	System	09 Oct 2020 14:45:51

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T09:45:13', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '6f8037ae-f282-430c-8fb6-a3beee1c1f64' User entered '09 Oct 2020 09:45'	(b) (4), (b) (6) System	09 Oct 2020 14:45:51
	System	09 Oct 2020 14:45:51

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '08 Oct 2020 12:00'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '09 Oct 2020 11:59'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Oct 2020 21:18:33
User entered 'Day 5'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T20:00:25', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'bbc2b753-9047-408d-8ffa-374db091ca5c' User entered 'None (1)'	(b) (4), (b) (6) System	10 Oct 2020 01:00:36
	System	10 Oct 2020 01:00:36

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:50:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T20:00:26', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'bbc2b753-9047-408d-8ffa-374db091ca5c' User entered 'No (N)'	(b) (4), (b) (6) System	10 Oct 2020 01:00:36
	System	10 Oct 2020 01:00:36

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T20:00:27', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'bbc2b753-9047-408d-8ffa-374db091ca5c' User entered 'No (N)'	(b) (4), (b) (6) System	10 Oct 2020 01:00:36
	System	10 Oct 2020 01:00:36

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T20:00:28', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'bbc2b753-9047-408d-8ffa-374db091ca5c' User entered 'None (1)'	(b) (4), (b) (6) System	10 Oct 2020 01:00:36
	System	10 Oct 2020 01:00:36

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T20:00:30', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'bbc2b753-9047-408d-8ffa-374db091ca5c' User entered '09 Oct 2020 20:00'	(b) (4), (b) (6) System	10 Oct 2020 01:00:36
	System	10 Oct 2020 01:00:36

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '09 Oct 2020 12:00'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '10 Oct 2020 11:59'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Oct 2020 21:18:33
User entered 'Day 6'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-10T23:42:18', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '504b89ae-cd66-4da1-ab98-ee10acbca99e' User entered 'None (1)'	(b) (4), (b) (6) System	11 Oct 2020 04:42:30
	System	11 Oct 2020 04:42:30

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:50:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-10T23:42:20', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '504b89ae-cd66-4da1-ab98-ee10acbca99e' User entered 'No (N)'	(b) (4), (b) (6) System	11 Oct 2020 04:42:30
	System	11 Oct 2020 04:42:30

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-10T23:42:22', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '504b89ae-cd66-4da1-ab98-ee10acbca99e' User entered 'No (N)'	(b) (4), (b) (6) System	11 Oct 2020 04:42:30
	System	11 Oct 2020 04:42:30

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-10T23:42:24', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '504b89ae-cd66-4da1-ab98-ee10acbca99e' User entered 'None (1)'	(b) (4), (b) (6) System	11 Oct 2020 04:42:30
	System	11 Oct 2020 04:42:30

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-10T23:42:26', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '504b89ae-cd66-4da1-ab98-ee10acbca99e' User entered '10 Oct 2020 23:42'	(b) (4), (b) (6) System	11 Oct 2020 04:42:30
	System	11 Oct 2020 04:42:30

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '10 Oct 2020 12:00'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '11 Oct 2020 11:59'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Oct 2020 21:18:33
User entered 'Day 7'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-11T20:01:36', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '7f1ebbd7-8d5c-4e1a-9f16-4e43106fa68e' User entered 'None (1)'	(b) (4), (b) (6) System	12 Oct 2020 01:01:48
	System	12 Oct 2020 01:01:48

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:50:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-11T20:01:39', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '7f1ebbd7-8d5c-4e1a-9f16-4e43106fa68e' User entered 'No (N)'	(b) (4), (b) (6) System	12 Oct 2020 01:01:48
	System	12 Oct 2020 01:01:48

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-11T20:01:40', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '7f1ebbd7-8d5c-4e1a-9f16-4e43106fa68e' User entered 'No (N)'	(b) (4), (b) (6) System	12 Oct 2020 01:01:48
	System	12 Oct 2020 01:01:48

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:50:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-11T20:01:42', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '7f1ebbd7-8d5c-4e1a-9f16-4e43106fa68e' User entered 'None (1)'	(b) (4), (b) (6) System	12 Oct 2020 01:01:48
	System	12 Oct 2020 01:01:48

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:50:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-11T20:01:44', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '7f1ebbd7-8d5c-4e1a-9f16-4e43106fa68e' User entered '11 Oct 2020 20:01'	(b) (4), (b) (6) System	12 Oct 2020 01:01:48
	System	12 Oct 2020 01:01:48

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '11 Oct 2020 12:00'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '12 Oct 2020 11:59'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Oct 2020 21:18:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-05T19:05:42', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '78fe45ae-f7a7-445a-b8a3-256b6417b066' User entered 'None (0)'	(b) (4), (b) (6) System	06 Oct 2020 00:05:54
	System	06 Oct 2020 00:05:54

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-05T19:05:43', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '78fe45ae-f7a7-445a-b8a3-256b6417b066' User entered 'None (0)'	(b) (4), (b) (6) System	06 Oct 2020 00:05:54
	System	06 Oct 2020 00:05:54

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-05T19:05:44', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '78fe45ae-f7a7-445a-b8a3-256b6417b066' User entered 'None (0)'	(b) (4), (b) (6) System	06 Oct 2020 00:05:54
	System	06 Oct 2020 00:05:54

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-05T19:05:45', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '78fe45ae-f7a7-445a-b8a3-256b6417b066' User entered 'None (0)'	(b) (4), (b) (6) System	06 Oct 2020 00:05:54
	System	06 Oct 2020 00:05:54

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-05T19:05:46', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '78fe45ae-f7a7-445a-b8a3-256b6417b066' User entered 'None (0)'	(b) (4), (b) (6) System	06 Oct 2020 00:05:54
	System	06 Oct 2020 00:05:54

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-05T19:05:47', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '78fe45ae-f7a7-445a-b8a3-256b6417b066' User entered 'None (0)'	(b) (4), (b) (6) System	06 Oct 2020 00:05:54
	System	06 Oct 2020 00:05:54

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-05T19:05:49', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '78fe45ae-f7a7-445a-b8a3-256b6417b066' User entered 'No (N)'	(b) (4), (b) (6) System	06 Oct 2020 00:05:54
	System	06 Oct 2020 00:05:54

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-05T19:05:51', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '78fe45ae-f7a7-445a-b8a3-256b6417b066' User entered '05 Oct 2020 19:05'	(b) (4), (b) (6) System	06 Oct 2020 00:05:54
	System	06 Oct 2020 00:05:54

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
User entered '05 Oct 2020 16:40'	System	05 Oct 2020 21:29:54
User entered '05 Oct 2020 16:33'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
User entered '05 Oct 2020 19:10'	System	05 Oct 2020 21:29:54
User entered '05 Oct 2020 19:03'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Oct 2020 21:18:33
User entered 'Day 1, after vaccination (at home)'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:13:16

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:13:16

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:13:16

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:13:16

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:13:16

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

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) (b) (4), (b) (6)	25 Feb 2021 22:13:16

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:13:16

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
User entered '05 Oct 2020 20:05'	System	05 Oct 2020 21:29:54
User entered '05 Oct 2020 19:58'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '06 Oct 2020 11:59'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Oct 2020 21:18:33
User entered 'Day 2'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:50:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-06T20:08:35', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '08b259e7-fefb-44ea-874b-137fecba9d75' User entered 'None (0)'	(b) (4), (b) (6) System	07 Oct 2020 01:08:58
	System	07 Oct 2020 01:08:58

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:50:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-06T20:08:36', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '08b259e7-fefb-44ea-874b-137fecba9d75' User entered 'None (0)'	(b) (4), (b) (6) System	07 Oct 2020 01:08:58
	System	07 Oct 2020 01:08:58

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:50:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-06T20:08:41', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '08b259e7-fefb-44ea-874b-137fecba9d75'	(b) (4), (b) (6)	07 Oct 2020 01:08:58
User entered 'No interference with activity (1)'	System	07 Oct 2020 01:08:58

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:50:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-06T20:08:47', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '08b259e7-fefb-44ea-874b-137fecba9d75' User entered 'None (0)'	(b) (4), (b) (6) System	07 Oct 2020 01:08:58
	System	07 Oct 2020 01:08:58

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:50:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-06T20:08:48', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '08b259e7-fefb-44ea-874b-137fecba9d75' User entered 'None (0)'	(b) (4), (b) (6) System	07 Oct 2020 01:08:58
	System	07 Oct 2020 01:08:58

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:50:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-06T20:08:50', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '08b259e7-fefb-44ea-874b-137fecba9d75' User entered 'None (0)'	(b) (4), (b) (6) System	07 Oct 2020 01:08:58
	System	07 Oct 2020 01:08:58

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-06T20:08:53', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '08b259e7-fefb-44ea-874b-137fecba9d75' User entered 'No (N)'	(b) (4), (b) (6) System	07 Oct 2020 01:08:58
	System	07 Oct 2020 01:08:58

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:50:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-06T20:08:55', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '08b259e7-fefb-44ea-874b-137fecba9d75' User entered '06 Oct 2020 20:08'	(b) (4), (b) (6) System	07 Oct 2020 01:08:58
	System	07 Oct 2020 01:08:58

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '06 Oct 2020 12:00'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '07 Oct 2020 11:59'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Oct 2020 21:18:33
User entered 'Day 3'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:50:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-07T22:41:58', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '0e333245-5129-473f-911e-9d4606660e56' User entered 'None (0)'	(b) (4), (b) (6) System	08 Oct 2020 03:42:13
	System	08 Oct 2020 03:42:13

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:50:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-07T22:42:00', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '0e333245-5129-473f-911e-9d4606660e56' User entered 'No interference with activity (1)'	(b) (4), (b) (6) System	08 Oct 2020 03:42:13
	System	08 Oct 2020 03:42:13

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:50:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-07T22:42:01', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '0e333245-5129-473f-911e-9d4606660e56' User entered 'No interference with activity (1)'	(b) (4), (b) (6) System	08 Oct 2020 03:42:13
	System	08 Oct 2020 03:42:13

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:50:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-07T22:42:02', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '0e333245-5129-473f-911e-9d4606660e56'	(b) (4), (b) (6)	08 Oct 2020 03:42:13
User entered 'No interference with activity (1)'	System	08 Oct 2020 03:42:13

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:50:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-07T22:42:04', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '0e333245-5129-473f-911e-9d4606660e56' User entered 'None (0)'	(b) (4), (b) (6) System	08 Oct 2020 03:42:13
	System	08 Oct 2020 03:42:13

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:50:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-07T22:42:05', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '0e333245-5129-473f-911e-9d4606660e56' User entered 'None (0)'	(b) (4), (b) (6) System	08 Oct 2020 03:42:13
	System	08 Oct 2020 03:42:13

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-07T22:42:08', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '0e333245-5129-473f-911e-9d4606660e56' User entered 'No (N)'	(b) (4), (b) (6) System	08 Oct 2020 03:42:13
	System	08 Oct 2020 03:42:13

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:50:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-07T22:42:10', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '0e333245-5129-473f-911e-9d4606660e56' User entered '07 Oct 2020 22:42'	(b) (4), (b) (6) System	08 Oct 2020 03:42:13
	System	08 Oct 2020 03:42:13

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '07 Oct 2020 12:00'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '08 Oct 2020 11:59'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Oct 2020 21:18:33
User entered 'Day 4'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:50:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T09:45:16', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'ecd470d5-f2b7-4572-bbc4-cbfc51d38cb2' User entered 'None (0)'	(b) (4), (b) (6) System	09 Oct 2020 14:45:52
	System	09 Oct 2020 14:45:52

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:50:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T09:45:17', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'ecd470d5-f2b7-4572-bbc4-cbfc51d38cb2' User entered 'None (0)'	(b) (4), (b) (6) System	09 Oct 2020 14:45:52
	System	09 Oct 2020 14:45:52

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:50:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T09:45:18', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'ecd470d5-f2b7-4572-bbc4-cbfc51d38cb2' User entered 'None (0)'	(b) (4), (b) (6) System	09 Oct 2020 14:45:52
	System	09 Oct 2020 14:45:52

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:50:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T09:45:19', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'ecd470d5-f2b7-4572-bbc4-cbfc51d38cb2' User entered 'None (0)'	(b) (4), (b) (6) System	09 Oct 2020 14:45:52
	System	09 Oct 2020 14:45:52

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:50:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T09:45:20', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'ecd470d5-f2b7-4572-bbc4-cbfc51d38cb2' User entered 'None (0)'	(b) (4), (b) (6) System	09 Oct 2020 14:45:52
	System	09 Oct 2020 14:45:52

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:50:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T09:45:20', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'ecd470d5-f2b7-4572-bbc4-cbfc51d38cb2' User entered 'None (0)'	(b) (4), (b) (6) System	09 Oct 2020 14:45:52
	System	09 Oct 2020 14:45:52

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T09:45:22', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'ecd470d5-f2b7-4572-bbc4-cbfc51d38cb2' User entered 'No (N)'	(b) (4), (b) (6) System	09 Oct 2020 14:45:52
	System	09 Oct 2020 14:45:52

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:50:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T09:45:24', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'ecd470d5-f2b7-4572-bbc4-cbfc51d38cb2' User entered '09 Oct 2020 09:45'	(b) (4), (b) (6) System	09 Oct 2020 14:45:52
	System	09 Oct 2020 14:45:52

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '08 Oct 2020 12:00'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '09 Oct 2020 11:59'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Oct 2020 21:18:33
User entered 'Day 5'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:50:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T20:00:32', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '31161a03-60d2-4ba1-a22f-5842831a39d8' User entered 'None (0)'	(b) (4), (b) (6) System	10 Oct 2020 01:00:42
	System	10 Oct 2020 01:00:42

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:50:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T20:00:33', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '31161a03-60d2-4ba1-a22f-5842831a39d8' User entered 'None (0)'	(b) (4), (b) (6) System	10 Oct 2020 01:00:42
	System	10 Oct 2020 01:00:42

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:50:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T20:00:33', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '31161a03-60d2-4ba1-a22f-5842831a39d8' User entered 'None (0)'	(b) (4), (b) (6) System	10 Oct 2020 01:00:42
	System	10 Oct 2020 01:00:42

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:50:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T20:00:34', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '31161a03-60d2-4ba1-a22f-5842831a39d8' User entered 'None (0)'	(b) (4), (b) (6) System	10 Oct 2020 01:00:42
	System	10 Oct 2020 01:00:42

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:50:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T20:00:35', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '31161a03-60d2-4ba1-a22f-5842831a39d8' User entered 'None (0)'	(b) (4), (b) (6) System	10 Oct 2020 01:00:42
	System	10 Oct 2020 01:00:42

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:50:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T20:00:36', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '31161a03-60d2-4ba1-a22f-5842831a39d8' User entered 'None (0)'	(b) (4), (b) (6) System	10 Oct 2020 01:00:42
	System	10 Oct 2020 01:00:42

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T20:00:37', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '31161a03-60d2-4ba1-a22f-5842831a39d8' User entered 'No (N)'	(b) (4), (b) (6) System	10 Oct 2020 01:00:42
	System	10 Oct 2020 01:00:42

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:50:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-09T20:00:39', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '31161a03-60d2-4ba1-a22f-5842831a39d8' User entered '09 Oct 2020 20:00'	(b) (4), (b) (6) System	10 Oct 2020 01:00:42
	System	10 Oct 2020 01:00:42

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '09 Oct 2020 12:00'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '10 Oct 2020 11:59'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Oct 2020 21:18:33
User entered 'Day 6'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:50:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-10T23:42:28', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'f63ec4af-dda3-4b1d-b6e1-d7e879896630' User entered 'None (0)'	(b) (4), (b) (6) System	11 Oct 2020 04:42:42
	System	11 Oct 2020 04:42:42

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:50:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-10T23:42:29', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'f63ec4af-dda3-4b1d-b6e1-d7e879896630' User entered 'None (0)'	(b) (4), (b) (6) System	11 Oct 2020 04:42:42
	System	11 Oct 2020 04:42:42

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:50:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-10T23:42:31', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'f63ec4af-dda3-4b1d-b6e1-d7e879896630' User entered 'None (0)'	(b) (4), (b) (6) System	11 Oct 2020 04:42:42
	System	11 Oct 2020 04:42:42

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:50:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-10T23:42:32', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'f63ec4af-dda3-4b1d-b6e1-d7e879896630' User entered 'None (0)'	(b) (4), (b) (6) System	11 Oct 2020 04:42:42
	System	11 Oct 2020 04:42:42

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:50:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-10T23:42:33', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'f63ec4af-dda3-4b1d-b6e1-d7e879896630' User entered 'None (0)'	(b) (4), (b) (6) System	11 Oct 2020 04:42:42
	System	11 Oct 2020 04:42:42

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:50:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-10T23:42:34', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'f63ec4af-dda3-4b1d-b6e1-d7e879896630' User entered 'None (0)'	(b) (4), (b) (6) System	11 Oct 2020 04:42:42
	System	11 Oct 2020 04:42:42

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-10T23:42:36', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'f63ec4af-dda3-4b1d-b6e1-d7e879896630' User entered 'No (N)'	(b) (4), (b) (6) System	11 Oct 2020 04:42:42
	System	11 Oct 2020 04:42:42

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:50:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-10T23:42:38', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'f63ec4af-dda3-4b1d-b6e1-d7e879896630' User entered '10 Oct 2020 23:42'	(b) (4), (b) (6) System	11 Oct 2020 04:42:42
	System	11 Oct 2020 04:42:42

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '10 Oct 2020 12:00'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '11 Oct 2020 11:59'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
	(b) (4), (b) (6)	
Data entry locked.	System	05 Oct 2020 21:18:33
User entered 'Day 7'	System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:50:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-11T20:01:47', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '9f68f6ac-e29f-4ca0-a361-f5e568057973' User entered 'None (0)'	(b) (4), (b) (6) System	12 Oct 2020 01:02:14
	System	12 Oct 2020 01:02:14

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:50:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-11T20:01:48', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '9f68f6ac-e29f-4ca0-a361-f5e568057973' User entered 'None (0)'	(b) (4), (b) (6) System	12 Oct 2020 01:02:14
	System	12 Oct 2020 01:02:14

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:50:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-11T20:01:50', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '9f68f6ac-e29f-4ca0-a361-f5e568057973' User entered 'None (0)'	(b) (4), (b) (6) System	12 Oct 2020 01:02:14
	System	12 Oct 2020 01:02:14

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:50:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-11T20:01:51', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '9f68f6ac-e29f-4ca0-a361-f5e568057973' User entered 'None (0)'	(b) (4), (b) (6) System	12 Oct 2020 01:02:14
	System	12 Oct 2020 01:02:14

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:50:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-11T20:01:52', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '9f68f6ac-e29f-4ca0-a361-f5e568057973' User entered 'None (0)'	(b) (4), (b) (6) System	12 Oct 2020 01:02:14
	System	12 Oct 2020 01:02:14

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:50:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-11T20:01:54', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '9f68f6ac-e29f-4ca0-a361-f5e568057973' User entered 'None (0)'	(b) (4), (b) (6) System	12 Oct 2020 01:02:14
	System	12 Oct 2020 01:02:14

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-11T20:02:11', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '9f68f6ac-e29f-4ca0-a361-f5e568057973' User entered 'No (N)'	(b) (4), (b) (6) System	12 Oct 2020 01:02:14
	System	12 Oct 2020 01:02:14

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:50:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-10-11T20:02:12', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '9f68f6ac-e29f-4ca0-a361-f5e568057973' User entered '11 Oct 2020 20:02'	(b) (4), (b) (6) System	12 Oct 2020 01:02:14
	System	12 Oct 2020 01:02:14

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:50:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '11 Oct 2020 12:00'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:50:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:13:16
User entered '12 Oct 2020 11:59'	(b) (4), (b) (6) System	05 Oct 2020 21:18:33

US3492061

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:45:45

US3492061

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '14 Oct 2020'	(b) (4) Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:45:45

US3492061

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:45:45

US3492061

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered empty.	(b) (4) Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:45:45

US3492061

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:47:34

US3492061

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User entered 'I'	(b) (4), (b) (6) System	15 Oct 2020 15:47:34

US3492061

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	21 Oct 2020 15:42:40

US3492061

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '20 Oct 2020'	(b) (4) Lorna Sanchez McCann (b) (4)	21 Oct 2020 15:42:40

US3492061

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lorna Sanchez McCann (b) (4)	21 Oct 2020 15:42:40

US3492061

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered empty.	(b) (4) Lorna Sanchez McCann (b) (4)	21 Oct 2020 15:42:40

US3492061

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	19 Oct 2020 18:38:47
	(b) (4)	

US3492061

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User entered 'I'	(b) (4), (b) (6) System	19 Oct 2020 18:38:47

US3492061

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	27 Oct 2020 14:47:38

US3492061

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '26 Oct 2020'	(b) (4) Nusirat Williams (b) (4)	27 Oct 2020 14:47:38

US3492061

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nusirat Williams (b) (4) (b) (4)	27 Oct 2020 14:47:38

US3492061

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered empty.	(b) (4) Nusirat Williams (b) (4)	27 Oct 2020 14:47:38

US3492061

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	27 Oct 2020 14:47:43

US3492061

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User entered 'I'	(b) (4), (b) (6) System	27 Oct 2020 14:47:43

US3492061

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:50:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:20:50

US3492061

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered '2 Nov 2020'	(b) (4) Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:20:50

US3492061

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered 'Clinic (Clinic)'	(b) (4) Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:20:50

US3492061

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:50:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User entered 'VISIT3'	(b) (4), (b) (6) System	02 Nov 2020 19:20:50

US3492061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:21:34

US3492061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered '2 Nov 2020'	(b) (4) Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:21:34

US3492061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered '12:50'	(b) (4) Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:21:34

US3492061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User entered '2 Nov 2020 12:50'	(b) (4), (b) (6) System	02 Nov 2020 19:21:34

US3492061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered '97.6' F	(b) (4) Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:21:34

US3492061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered 'Other (Other)'	(b) (4) Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:21:34

US3492061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered 'tympanic'	(b) (4) Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:21:34

US3492061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered '66'	(b) (4) Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:21:34

US3492061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User entered 'bpm'	(b) (4), (b) (6) System	02 Nov 2020 19:21:34

US3492061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered '16'	(b) (4) Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:21:34

US3492061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User entered 'breaths/min'	(b) (4), (b) (6) System	02 Nov 2020 19:21:34

US3492061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered '125'	(b) (4) Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:21:34

US3492061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User entered 'mmHg'	(b) (4), (b) (6) System	02 Nov 2020 19:21:34

US3492061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered '74'	(b) (4) Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:21:34

US3492061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User entered 'mmHg'	(b) (4), (b) (6) System	02 Nov 2020 19:21:34

US3492061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:36:08

US3492061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 15:36:08

US3492061

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:50:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:21:43

US3492061

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:50:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered '2 Nov 2020'	(b) (4) Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:21:43

US3492061

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:50:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:21:56

US3492061

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:50:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered '2 Nov 2020'	(b) (4) Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:21:56

US3492061

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered '13:00'	(b) (4) Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:21:56

US3492061

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User entered '2 Nov 2020 13:00'	(b) (4), (b) (6) System	02 Nov 2020 19:21:56

US3492061

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:57
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:22:03

US3492061

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:08
User entered '1'	(b) (4), (b) (6) System	02 Nov 2020 19:22:03

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24
Data entry locked.	System	05 Sep 2020 14:28:56
User entered 'Day 64'	System	05 Sep 2020 14:28:56

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24
Data entry locked.	System	05 Sep 2020 14:28:56
User entered '05 Nov 2020 00:01'	System	05 Sep 2020 14:28:56

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24
Data entry locked.	System	05 Sep 2020 14:28:56
User entered '09 Nov 2020 23:59'	System	05 Sep 2020 14:28:56

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24
Data entry locked.	System	05 Sep 2020 14:28:56
User entered 'Day 71'	System	05 Sep 2020 14:28:56

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24
Data entry locked.	System	05 Sep 2020 14:28:56
User entered '12 Nov 2020 00:01'	System	05 Sep 2020 14:28:56

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24
Data entry locked.	System	05 Sep 2020 14:28:56
User entered '16 Nov 2020 23:59'	System	05 Sep 2020 14:28:56

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24
Data entry locked.	System	05 Sep 2020 14:28:56
User entered 'Day 78'	System	05 Sep 2020 14:28:56

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24
Data entry locked.	System	05 Sep 2020 14:28:56
User entered '19 Nov 2020 00:01'	System	05 Sep 2020 14:28:56

US3492061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:48:24
Data entry locked.	System	05 Sep 2020 14:28:56
User entered '23 Nov 2020 23:59'	System	05 Sep 2020 14:28:56

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '23 Nov 2020 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '27 Nov 2020 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '30 Nov 2020 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '04 Dec 2020 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[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 (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-12-07T07:11:16', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '90bb31d4-20d5-46b3-a59c-c5c5c34a4cce' User entered 'No (N)'	System	07 Dec 2020 13:12:41
	System	07 Dec 2020 13:12:41

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

Have you been exposed to someone with 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 (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-12-07T07:12:34', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '90bb31d4-20d5-46b3-a59c-c5c5c34a4cce' User entered 'No (N)'	System	07 Dec 2020 13:12:41
	System	07 Dec 2020 13:12:41

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Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:50:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2020-12-07T07:12:37', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '90bb31d4-20d5-46b3-a59c-c5c5c34a4cce' User entered '07 Dec 2020 07:12:37'	System	07 Dec 2020 13:12:41
	System	07 Dec 2020 13:12:41

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '07 Dec 2020 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '11 Dec 2020 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '14 Dec 2020 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '18 Dec 2020 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '21 Dec 2020 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '25 Dec 2020 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '28 Dec 2020 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '01 Jan 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[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 (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2021-01-04T11:12:33', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '3e3107d7-88c3-42a0-8675-5a76ba5fe1a4'	System	04 Jan 2021 17:12:43
User entered 'No (N)'	System	04 Jan 2021 17:12:43

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Have you been exposed to someone with 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 (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2021-01-04T11:12:36', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '3e3107d7-88c3-42a0-8675-5a76ba5fe1a4'	System	04 Jan 2021 17:12:43
User entered 'No (N)'	System	04 Jan 2021 17:12:43

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FEA01981-BB64-4EFF-9744-6E93D50319A8)', Time: '2021-01-04T11:12:39', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '3e3107d7-88c3-42a0-8675-5a76ba5fe1a4' User entered '04 Jan 2021 11:12:39'	System	04 Jan 2021 17:12:43
	System	04 Jan 2021 17:12:43

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '04 Jan 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '08 Jan 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[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 (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-01-15T20:12:30', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'fab77d04-76e0-420f-aeac-f94d4990f756'	System	16 Jan 2021 02:12:45
User entered 'No (N)'	System	16 Jan 2021 02:12:45

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Have you been exposed to someone with 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 (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-01-15T20:12:32', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'fab77d04-76e0-420f-aeac-f94d4990f756'	System	16 Jan 2021 02:12:45
User entered 'No (N)'	System	16 Jan 2021 02:12:45

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-01-15T20:12:34', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'fab77d04-76e0-420f-aeac-f94d4990f756' User entered '15 Jan 2021 20:12:34'	System	16 Jan 2021 02:12:45
	System	16 Jan 2021 02:12:45

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '11 Jan 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '15 Jan 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[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 (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-01-20T13:00:47', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'e7640c2c-62b5-4f1e-a9db-2e0b388ed170' User entered 'No (N)'	System	20 Jan 2021 19:00:53
	System	20 Jan 2021 19:00:53

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Have you been exposed to someone with 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 (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-01-20T13:00:48', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'e7640c2c-62b5-4f1e-a9db-2e0b388ed170' User entered 'No (N)'	System	20 Jan 2021 19:00:53
	System	20 Jan 2021 19:00:53

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-01-20T13:00:50', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'e7640c2c-62b5-4f1e-a9db-2e0b388ed170'	System	20 Jan 2021 19:00:53
User entered '20 Jan 2021 13:00:50'	System	20 Jan 2021 19:00:53

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '18 Jan 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '22 Jan 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[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 (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-01-26T22:14:19', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '68078144-0493-4ab8-8f07-17561b94683d' User entered 'No (N)'	System	27 Jan 2021 04:14:27
	System	27 Jan 2021 04:14:27

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Have you been exposed to someone with 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 (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-01-26T22:14:20', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '68078144-0493-4ab8-8f07-17561b94683d' User entered 'No (N)'	System	27 Jan 2021 04:14:27

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-01-26T22:14:22', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '68078144-0493-4ab8-8f07-17561b94683d' User entered '26 Jan 2021 22:14:22'	System	27 Jan 2021 04:14:27

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '25 Jan 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '29 Jan 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[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 (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-02-03T17:35:53', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '45ddceb2-35a0-48e9-919d-c84ad2967828' User entered 'No (N)'	System	03 Feb 2021 23:36:00
	System	03 Feb 2021 23:36:00

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Have you been exposed to someone with 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 (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-02-03T17:35:54', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '45ddceb2-35a0-48e9-919d-c84ad2967828' User entered 'No (N)'	System	03 Feb 2021 23:36:00
	System	03 Feb 2021 23:36:00

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-02-03T17:35:56', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '45ddceb2-35a0-48e9-919d-c84ad2967828' User entered '03 Feb 2021 17:35:56'	System	03 Feb 2021 23:36:00
	System	03 Feb 2021 23:36:00

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '01 Feb 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '05 Feb 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[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 (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-02-12T07:09:30', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '1e8d7919-30b1-4e37-9f81-a02b28b74af7' User entered 'No (N)'	System	12 Feb 2021 17:17:58
	System	12 Feb 2021 17:17:58

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Have you been exposed to someone with 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 (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-02-12T07:09:31', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '1e8d7919-30b1-4e37-9f81-a02b28b74af7' User entered 'No (N)'	System	12 Feb 2021 17:17:58
	System	12 Feb 2021 17:17:58

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-02-12T07:09:33', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '1e8d7919-30b1-4e37-9f81-a02b28b74af7'	System	12 Feb 2021 17:17:58
User entered '12 Feb 2021 07:09:33'	System	12 Feb 2021 17:17:58

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '08 Feb 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '12 Feb 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[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 (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-02-19T17:39:35', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '2ba79695-9442-4d78-a658-0fb649740143'	System	19 Feb 2021 23:39:53
User entered 'No (N)'	System	19 Feb 2021 23:39:53

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Have you been exposed to someone with 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 (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-02-19T17:39:44', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '2ba79695-9442-4d78-a658-0fb649740143'	System	19 Feb 2021 23:39:53
User entered 'No (N)'	System	19 Feb 2021 23:39:53

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-02-19T17:39:49', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '2ba79695-9442-4d78-a658-0fb649740143'	System	19 Feb 2021 23:39:53
User entered '19 Feb 2021 17:39:49'	System	19 Feb 2021 23:39:53

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '15 Feb 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '19 Feb 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[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 (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-02-23T09:53:11-06:00', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'db13183a-f1b2-45bd-bcef-c9157a4f62a6'	System	23 Feb 2021 15:53:16
User entered 'No (N)'	System	23 Feb 2021 15:53:16

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

Have you been exposed to someone with 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 (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-02-23T09:53:12-06:00', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'db13183a-f1b2-45bd-bcef-c9157a4f62a6'	System	23 Feb 2021 15:53:16
User entered 'No (N)'	System	23 Feb 2021 15:53:16

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-02-23T09:53:14-06:00', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'db13183a-f1b2-45bd-bcef-c9157a4f62a6'	System	23 Feb 2021 15:53:16
User entered '23 Feb 2021 15:53:14'	System	23 Feb 2021 15:53:16

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '22 Feb 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '26 Feb 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[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 (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-03-01T11:52:45-06:00', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '7ae29297-0151-48b0-932e-f2a171047852'	System	01 Mar 2021 17:52:51
User entered 'No (N)'	System	01 Mar 2021 17:52:51

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Have you been exposed to someone with 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 (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-03-01T11:52:47-06:00', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '7ae29297-0151-48b0-932e-f2a171047852'	System	01 Mar 2021 17:52:51
User entered 'No (N)'	System	01 Mar 2021 17:52:51

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-03-01T11:52:49-06:00', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '7ae29297-0151-48b0-932e-f2a171047852' User entered '01 Mar 2021 17:52:49'	System	01 Mar 2021 17:52:51
	System	01 Mar 2021 17:52:51

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '01 Mar 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '05 Mar 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[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 (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-03-11T15:54:26-06:00', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'a9d81b60-c951-483a-81e4-17179dd8981b'	System	11 Mar 2021 21:54:34
User entered 'No (N)'	System	11 Mar 2021 21:54:34

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Have you been exposed to someone with 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 (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-03-11T15:54:27-06:00', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'a9d81b60-c951-483a-81e4-17179dd8981b'	System	11 Mar 2021 21:54:34
User entered 'No (N)'	System	11 Mar 2021 21:54:34

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-03-11T15:54:29-06:00', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'a9d81b60-c951-483a-81e4-17179dd8981b' User entered '11 Mar 2021 15:54:29'	System	11 Mar 2021 21:54:34
	System	11 Mar 2021 21:54:34

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '08 Mar 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '12 Mar 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[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 (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-03-16T08:39:30-05:00', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '24fba486-7a4c-45c8-86c5-487021e3ee40'	System	16 Mar 2021 13:39:36
User entered 'No (N)'	System	16 Mar 2021 13:39:36

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Have you been exposed to someone with 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 (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-03-16T08:39:31-05:00', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '24fba486-7a4c-45c8-86c5-487021e3ee40'	System	16 Mar 2021 13:39:36
User entered 'No (N)'	System	16 Mar 2021 13:39:36

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-03-16T08:39:33-05:00', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '24fba486-7a4c-45c8-86c5-487021e3ee40'	System	16 Mar 2021 13:39:36
User entered '16 Mar 2021 08:39:33'	System	16 Mar 2021 13:39:36

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '15 Mar 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '19 Mar 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '22 Mar 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '26 Mar 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[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 (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-04-01T15:46:23-05:00', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '8ebeee58-2f1e-4f09-ae52-e8e782e7e464'	System	01 Apr 2021 20:46:30
User entered 'No (N)'	System	01 Apr 2021 20:46:30

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Have you been exposed to someone with 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 (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-04-01T15:46:24-05:00', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '8ebeee58-2f1e-4f09-ae52-e8e782e7e464' User entered 'No (N)'	System	01 Apr 2021 20:46:30
	System	01 Apr 2021 20:46:30

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-04-01T15:46:26-05:00', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '8ebeee58-2f1e-4f09-ae52-e8e782e7e464'	System	01 Apr 2021 20:46:30
User entered '01 Apr 2021 15:46:26'	System	01 Apr 2021 20:46:30

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '29 Mar 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '02 Apr 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Headache](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Apr 2021 18:18:27
	(b) (4), (b) (6)	

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[New loss of taste](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Apr 2021 18:18:27
	(b) (4), (b) (6)	

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[New loss of smell](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Apr 2021 18:18:27
	(b) (4), (b) (6)	

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Sore throat](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Apr 2021 18:18:27
	(b) (4), (b) (6)	

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Congestion](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Apr 2021 18:18:27
	(b) (4), (b) (6)	

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Runny nose](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Apr 2021 18:18:27
	(b) (4), (b) (6)	

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Nausea](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Apr 2021 18:18:27
	(b) (4), (b) (6)	

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Vomiting](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Apr 2021 18:18:27
	(b) (4), (b) (6)	

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Diarrhea](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Apr 2021 18:18:27
	(b) (4), (b) (6)	

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '05 Apr 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '09 Apr 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '12 Apr 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '16 Apr 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[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 (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-04-22T14:59:55-05:00', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'bb0f6caa-4c1f-4b8a-8147-e2101893a0fd'	System	22 Apr 2021 20:00:00
User entered 'No (N)'	System	22 Apr 2021 20:00:00

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

Have you been exposed to someone with 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 (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-04-22T14:59:56-05:00', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'bb0f6caa-4c1f-4b8a-8147-e2101893a0fd' User entered 'No (N)'	System	22 Apr 2021 20:00:00
	System	22 Apr 2021 20:00:00

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-04-22T14:59:58-05:00', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: 'bb0f6caa-4c1f-4b8a-8147-e2101893a0fd' User entered '22 Apr 2021 14:59:58'	System	22 Apr 2021 20:00:00
	System	22 Apr 2021 20:00:00

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '19 Apr 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '23 Apr 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[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 (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-04-30T10:45:26-05:00', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '9572ff9b-760b-469e-8af1-8b1c652eea59'	System	30 Apr 2021 15:45:45
User entered 'No (N)'	System	30 Apr 2021 15:45:45

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Have you been exposed to someone with 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 (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-04-30T10:45:27-05:00', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '9572ff9b-760b-469e-8af1-8b1c652eea59'	System	30 Apr 2021 15:45:45
User entered 'No (N)'	System	30 Apr 2021 15:45:45

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-04-30T10:45:29-05:00', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '9572ff9b-760b-469e-8af1-8b1c652eea59' User entered '30 Apr 2021 10:45:29'	System	30 Apr 2021 15:45:45
	System	30 Apr 2021 15:45:45

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '26 Apr 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '30 Apr 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '03 May 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '07 May 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '10 May 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '14 May 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '17 May 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '21 May 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '24 May 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '28 May 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '31 May 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '04 Jun 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '07 Jun 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '11 Jun 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '14 Jun 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '18 Jun 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '21 Jun 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '25 Jun 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '28 Jun 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '02 Jul 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '05 Jul 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '09 Jul 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '12 Jul 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '16 Jul 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '19 Jul 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '23 Jul 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '26 Jul 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '30 Jul 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '02 Aug 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '06 Aug 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '09 Aug 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '13 Aug 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '16 Aug 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '20 Aug 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '23 Aug 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '27 Aug 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '30 Aug 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '03 Sep 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '06 Sep 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '10 Sep 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '13 Sep 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '17 Sep 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '20 Sep 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '24 Sep 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '27 Sep 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '01 Oct 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '04 Oct 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '08 Oct 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '11 Oct 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '15 Oct 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '18 Oct 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '22 Oct 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '25 Oct 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '29 Oct 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '01 Nov 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '05 Nov 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '08 Nov 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '12 Nov 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '15 Nov 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '19 Nov 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '22 Nov 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '26 Nov 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '29 Nov 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '03 Dec 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '06 Dec 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '10 Dec 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '13 Dec 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '17 Dec 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '20 Dec 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '24 Dec 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '27 Dec 2021 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '31 Dec 2021 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '03 Jan 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '07 Jan 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '10 Jan 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '14 Jan 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '17 Jan 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '21 Jan 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '24 Jan 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '28 Jan 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '31 Jan 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '04 Feb 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '07 Feb 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '11 Feb 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '14 Feb 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '18 Feb 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '21 Feb 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '25 Feb 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '28 Feb 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '04 Mar 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '07 Mar 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '11 Mar 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '14 Mar 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '18 Mar 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '21 Mar 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '25 Mar 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '28 Mar 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '01 Apr 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '04 Apr 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '08 Apr 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '11 Apr 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '15 Apr 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '18 Apr 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '22 Apr 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '25 Apr 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '29 Apr 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '02 May 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '06 May 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '09 May 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '13 May 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '16 May 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '20 May 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '23 May 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '27 May 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '30 May 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '03 Jun 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '06 Jun 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '10 Jun 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '13 Jun 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '17 Jun 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '20 Jun 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '24 Jun 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '27 Jun 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '01 Jul 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '04 Jul 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '08 Jul 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '11 Jul 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '15 Jul 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '18 Jul 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '22 Jul 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '25 Jul 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '29 Jul 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '01 Aug 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '05 Aug 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '08 Aug 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '12 Aug 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '15 Aug 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '19 Aug 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '22 Aug 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '26 Aug 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '29 Aug 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '02 Sep 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '05 Sep 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '09 Sep 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '12 Sep 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '16 Sep 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '19 Sep 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '23 Sep 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '26 Sep 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '30 Sep 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '03 Oct 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '07 Oct 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '10 Oct 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '14 Oct 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '17 Oct 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '21 Oct 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '24 Oct 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '28 Oct 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '31 Oct 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '04 Nov 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '07 Nov 2022 00:01'	System	20 Nov 2020 03:48:24

US3492061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:50:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:48:24
Amendment Manager: User entered '11 Nov 2022 23:59'	System	20 Nov 2020 03:48:24

US3492061

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:50:42

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)	26 Apr 2021 13:42:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-03-01T11:52:40-06:00', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '760a4d18-8f42-4676-98d2-72afaea4e340'	(b) (4), (b) (6)	
User entered 'No (N)'	System	01 Mar 2021 17:52:46

US3492061

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:50:42

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38D78ADB-8F1A-4827-94D6-C810EF710768)', Time: '2021-03-01T11:52:42-06:00', User OID: 'PatientReportedOutcome (US3492061)', ODM File OID: '760a4d18-8f42-4676-98d2-72afaea4e340' User entered '01 Mar 2021 17:52:42'	(b) (4), (b) (6) System	01 Mar 2021 17:52:46
	System	01 Mar 2021 17:52:46

US3492061

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	02 Dec 2020 15:05:38

US3492061

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '1 Dec 2020'	(b) (4) Lorna Sanchez McCann (b) (4)	02 Dec 2020 15:05:38

US3492061

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lorna Sanchez McCann (b) (4)	02 Dec 2020 15:05:38

US3492061

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered empty.	(b) (4) Lorna Sanchez McCann (b) (4)	02 Dec 2020 15:05:38

US3492061

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	01 Dec 2020 16:45:27

US3492061

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:05
User entered 'I'	(b) (4), (b) (6) System	01 Dec 2020 16:45:27

US3492061

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Yes (Y)'	Ian Feather (b) (4)	04 Jan 2021 17:15:53

US3492061

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '4 Jan 2021'	Ian Feather (b) (4)	04 Jan 2021 17:15:53

US3492061

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ian Feather (b) (4)	04 Jan 2021 17:15:53

US3492061

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered empty.	(b) (4) Ian Feather (b) (4)	04 Jan 2021 17:15:53
	(b) (4)	

US3492061

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Jan 2021 20:12:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Jan 2021 20:12:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Ian Feather (b) (4)	04 Jan 2021 20:12:44
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Jan 2021 17:15:56
User entered empty.	Ian Feather (b) (4)	04 Jan 2021 17:15:56
	(b) (4)	

US3492061

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:05
User entered '1'	(b) (4), (b) (6)	
	System	04 Jan 2021 20:12:44
User entered empty.	System	04 Jan 2021 17:15:56

US3492061

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:44
User entered 'Yes (Y)'	(b) (4) Nia Moragne-O'Neal (b) (4)	01 Mar 2021 17:57:02

US3492061

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:44
User entered '1 Feb 2021'	(b) (4) Nia Moragne-O'Neal (b) (4)	01 Mar 2021 17:57:02

US3492061

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nia Moragne-O'Neal (b) (4)	01 Mar 2021 17:57:02

US3492061

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:44
User entered empty.	(b) (4) Nia Moragne-O'Neal (b) (4)	01 Mar 2021 17:57:02

US3492061

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:44
User entered 'Yes (Y)'	(b) (4) Nia Moragne-O'Neal (b) (4)	01 Mar 2021 17:57:05

US3492061

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:05
User entered '1'	(b) (4), (b) (6) System	01 Mar 2021 17:57:05

US3492061

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:44
User entered 'Yes (Y)'	(b) (4) Nia Moragne-O'Neal (b) (4)	01 Mar 2021 17:57:43

US3492061

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:44
User entered '1 Mar 2021'	(b) (4) Nia Moragne-O'Neal (b) (4)	01 Mar 2021 17:57:43

US3492061

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nia Moragne-O'Neal (b) (4)	01 Mar 2021 17:57:43

US3492061

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:05
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:44
User entered empty.	(b) (4) Nia Moragne-O'Neal (b) (4)	01 Mar 2021 17:57:43

US3492061

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:05
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:40:44
	(b) (4)	
User entered 'Yes (Y)'	Nia Moragne-O'Neal	01 Mar 2021 17:57:47
	(b) (4)	

US3492061

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:05
User entered '1'	(b) (4), (b) (6) System	01 Mar 2021 17:57:47

US3492061

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:50:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:37
	(b) (4)	
User entered 'Yes (Y)'	Lorna Sanchez McCann	29 Mar 2021 14:11:11
	(b) (4)	

US3492061

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:37
	(b) (4)	
User entered '29 Mar 2021'	Lorna Sanchez McCann	29 Mar 2021 14:11:11
	(b) (4)	

US3492061

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:37
User entered 'Clinic (Clinic)'	(b) (4) Lorna Sanchez McCann (b) (4)	29 Mar 2021 14:11:11

US3492061

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:50:42

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	29 Mar 2021 14:11:11

US3492061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:37
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	29 Mar 2021 14:12:05

US3492061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:37
	(b) (4)	
User entered '29 Mar 2021'	Lorna Sanchez McCann	29 Mar 2021 14:12:05
	(b) (4)	

US3492061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:37
	(b) (4)	
User entered '08:55'	Lorna Sanchez McCann	29 Mar 2021 14:12:05
	(b) (4)	

US3492061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
User entered '29 Mar 2021 08:55'	System	29 Mar 2021 14:12:05

US3492061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:37
	(b) (4)	
User entered '97.9' F	Lorna Sanchez McCann	29 Mar 2021 14:12:05
	(b) (4)	

US3492061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:37
	(b) (4)	
User entered 'Other (Other)'	Lorna Sanchez McCann	29 Mar 2021 14:12:05
	(b) (4)	

US3492061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:37
User entered 'tympanic'	(b) (4) Lorna Sanchez McCann (b) (4)	29 Mar 2021 14:12:05

US3492061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:37
	(b) (4)	
User entered '71'	Lorna Sanchez McCann	29 Mar 2021 14:12:05
	(b) (4)	

US3492061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Mar 2021 14:12:05

US3492061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:37
	(b) (4)	
User entered '18'	Lorna Sanchez McCann	29 Mar 2021 14:12:05
	(b) (4)	

US3492061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Mar 2021 14:12:05

US3492061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:37
	(b) (4)	
User entered '114'	Lorna Sanchez McCann	29 Mar 2021 14:12:05
	(b) (4)	

US3492061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Mar 2021 14:12:05

US3492061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:37
	(b) (4)	
User entered '70'	Lorna Sanchez McCann	29 Mar 2021 14:12:05
	(b) (4)	

US3492061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:50:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Mar 2021 14:12:05

US3492061

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:50:42

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:37
	(b) (4)	
User entered 'Yes (Y)'	Lorna Sanchez McCann	29 Mar 2021 14:12:15
	(b) (4)	

US3492061

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:50:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:37
	(b) (4)	
User entered '29 Mar 2021'	Lorna Sanchez McCann	29 Mar 2021 14:12:15
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:50:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:37
	(b) (4)	
User entered 'Yes (Y)'	Lorna Sanchez McCann	29 Mar 2021 14:12:27
	(b) (4)	

US3492061

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:50:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:37
	(b) (4)	
User entered '29 Mar 2021'	Lorna Sanchez McCann	29 Mar 2021 14:12:27
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:37
	(b) (4)	
User entered '09:05'	Lorna Sanchez McCann	29 Mar 2021 14:12:27
	(b) (4)	

US3492061

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
User entered '29 Mar 2021 09:05'	System	29 Mar 2021 14:12:27

US3492061

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:37
	(b) (4)	
User entered 'Yes (Y)'	Lorna Sanchez McCann	29 Mar 2021 14:12:31
	(b) (4)	

US3492061

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 14:12:31

US3492061

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:44:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:34:08

US3492061

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:44:49
User entered '30 Apr 2021'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:34:08

US3492061

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:44:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:34:08

US3492061

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:50:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:44:49
User entered empty.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:34:08

US3492061

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:44:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:34:29

US3492061

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:50:42

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 18:34:29

US3492061

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

Form: Visit Date

Generated On: 11 Aug 2021 22:50:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4) (b) (4)	20 Jan 2021 19:30:38

US3492061

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

Form: Visit Date

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '20 Jan 2021'	(b) (4) Nusirat Williams (b) (4)	20 Jan 2021 19:30:38

US3492061

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

Form: Visit Date

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Clinic (Clinic)'	(b) (4) Nusirat Williams (b) (4) (b) (4)	20 Jan 2021 19:30:38

US3492061

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

Form: Visit Date

Generated On: 11 Aug 2021 22:50:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User entered 'UNBLND_DECIDE'	(b) (4), (b) (6) System	20 Jan 2021 19:30:38

US3492061

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

Form: Unblinding

Generated On: 11 Aug 2021 22:50:42

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered '20 Jan 2021' reason for change: Data Entry Error	Lorna Sanchez McCann	21 Jan 2021 20:19:16
	(b) (4)	
User entered '24 Dec 2020'	Nusirat Williams (b) (4)	20 Jan 2021 19:31:09
	(b) (4)	

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

Form: Unblinding

Generated On: 11 Aug 2021 22:50:42

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:44
User entered '0' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:36:50

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

Form: Unblinding

Generated On: 11 Aug 2021 22:50:42

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4) (b) (4)	20 Jan 2021 19:31:09

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

Form: Unblinding

Generated On: 11 Aug 2021 22:50:42

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:44
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 18:36:50

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

Form: Unblinding

Generated On: 11 Aug 2021 22:50:42

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '20 Jan 2021'	(b) (4) Nusirat Williams (b) (4) (b) (4)	20 Jan 2021 19:31:09

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

Form: Unblinding

Generated On: 11 Aug 2021 22:50:42

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Nusirat Williams (b) (4)	20 Jan 2021 19:31:09

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

Form: Unblinding

Generated On: 11 Aug 2021 22:50:42

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Nusirat Williams (b) (4)	20 Jan 2021 19:31:09

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

Form: Unblinding

Generated On: 11 Aug 2021 22:50:42

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Nusirat Williams (b) (4)	20 Jan 2021 19:31:09

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

Form: Unblinding

Generated On: 11 Aug 2021 22:50:42

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4) (b) (4)	20 Jan 2021 19:31:09

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

Form: Unblinding

Generated On: 11 Aug 2021 22:50:42

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User entered empty.	(b) (4), (b) (6) System	20 Jan 2021 19:31:09

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

Form: Unblinding

Generated On: 11 Aug 2021 22:50:42

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User entered empty.	(b) (4), (b) (6) System	20 Jan 2021 19:31:09

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:50:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	20 Jan 2021 19:31:29

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:50:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '20 Jan 2021'	(b) (4) Nusirat Williams (b) (4)	20 Jan 2021 19:31:29

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '13:20'	(b) (4) Nusirat Williams (b) (4) (b) (4)	20 Jan 2021 19:31:29

US3492061

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User entered '20 Jan 2021 13:20'	(b) (4), (b) (6) System	20 Jan 2021 19:31:29

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:50:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	20 Jan 2021 19:31:48

US3492061

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:50:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '20 Jan 2021'	(b) (4) Nusirat Williams (b) (4)	20 Jan 2021 19:31:48

US3492061

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '13:25'	(b) (4) Nusirat Williams (b) (4) (b) (4)	20 Jan 2021 19:31:48

US3492061

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:29
User entered '20 Jan 2021 13:25'	(b) (4), (b) (6) System	20 Jan 2021 19:31:48

US3492061

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:50:42

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:37
	(b) (4)	
Signature has been broken.	Marla Schwarber (b) (4)	07 Apr 2021 18:30:40
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Marla Schwarber (b) (4)	07 Apr 2021 18:30:40
	(b) (4)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'Yes (Y)'	Addis Mekonnen (b) (4)	11 Sep 2020 17:19:36
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:17:12
User closed query 'Per DM CLR: Per Diary Dose 1 Day 1, Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 13:45:11
Query 'Per DM CLR: Per Diary Dose 1 Day 1, Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'updated' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	08 Apr 2021 20:58:41
User opened query 'Per DM CLR: Per Diary Dose 1 Day 1, Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 03:34:11
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:19:30

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'Date corrected for ibuprofen to reflect diary. Reported to site 08OCT2020' (Site from DM).	Michelle Agnoli (b) (4)	19 Feb 2021 22:19:29
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 03:37:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	05 Sep 2020 16:02:01

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:50:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 20:35:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 20:35:50
Data point term sent to Coder Coding entries removed.	System Marla Schwarber (b) (4)	11 Sep 2020 20:34:07 11 Sep 2020 20:33:30
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Sep 2020 16:03:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Sep 2020 16:03:38
Data point term sent to Coder User entered 'omeprazole'	System Andrea Wendrow (b) (4)	05 Sep 2020 16:02:59 05 Sep 2020 16:02:57

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:50:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'No (N)'	Andrea Wendrow (b) (4)	05 Sep 2020 16:02:57
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:50:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'Gastroesophageal reflux disease'	Marla Schwarber (b) (4)	11 Sep 2020 20:33:30
reason for change: Data Entry Error	(b) (4)	
User entered 'GERD'	Andrea Wendrow (b) (4)	05 Sep 2020 16:02:57
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:50:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered '40'	Andrea Wendrow (b) (4)	05 Sep 2020 16:02:57
	(b) (4)	

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:50:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'mg (mg)'	Andrea Wendrow (b) (4)	05 Sep 2020 16:02:57
	(b) (4)	

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:50:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	05 Sep 2020 16:02:57
	(b) (4)	

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:50:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'once daily (QD)'	Andrea Wendrow (b) (4)	05 Sep 2020 16:02:57
	(b) (4)	

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:50:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	05 Sep 2020 16:02:57
	(b) (4)	

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:50:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'Oral (ORAL)'	Andrea Wendrow (b) (4)	05 Sep 2020 16:02:57
	(b) (4)	

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:50:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	05 Sep 2020 16:02:57
	(b) (4)	

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'UN UNK 2012'	Andrea Wendrow (b) (4)	05 Sep 2020 16:02:57
	(b) (4)	

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:50:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered '0'	Andrea Wendrow (b) (4)	05 Sep 2020 16:02:57
	(b) (4)	

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:50:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	05 Sep 2020 16:02:57
	(b) (4)	

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	05 Sep 2020 16:02:57
	(b) (4)	

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:50:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'No (N)'	Andrea Wendrow (b) (4)	05 Sep 2020 16:02:57
	(b) (4)	

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:50:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 16:02:57

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:50:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 16:02:57

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:50:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 16:02:57

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:50:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:49
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: LEVONORGESTREL, PRODUCTSYNONYM: LILETTA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Sep 2020 07:10:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Sep 2020 07:10:46
Data point term sent to Coder	System	11 Sep 2020 20:56:08
Coding entries removed.	Andrea Wendrow (b) (4) (b) (4)	11 Sep 2020 20:55:51
User entered 'Liletta (levonorgestrel) IUD' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	11 Sep 2020 20:55:51
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: LEVONORGESTREL, PRODUCTSYNONYM: MIRENA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 16:08:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 16:08:39
Data point term sent to Coder	System	05 Sep 2020 16:08:02
User entered 'Mirena IUD'	Andrea Wendrow (b) (4) (b) (4)	05 Sep 2020 16:07:09

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:50:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:49
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Yes (Y)'	(b) (4) Andrea Wendrow (b) (4)	05 Sep 2020 16:07:09

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:50:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:49
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Contraception'	(b) (4) Andrea Wendrow (b) (4)	05 Sep 2020 16:07:09

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:50:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:49
User signature succeeded.	(b) (4), (b) (6)	
	Richard Novak (b) (4)	15 Feb 2021 03:35:51
User closed query 'Per CDM: Please consider updating dose per administration field to a numerical value.' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	14 Sep 2020 10:31:58
Query 'Per CDM: Please consider updating dose per administration field to a numerical value.' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4)	11 Sep 2020 20:48:02
	(b) (4)	
User entered '52' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	11 Sep 2020 20:46:24
	(b) (4)	
User opened query 'Per CDM: Please consider updating dose per administration field to a numerical value.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 14:47:07
User entered 'other'	Andrea Wendrow (b) (4)	05 Sep 2020 16:07:09
	(b) (4)	

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:50:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:49
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'mg (mg)'	(b) (4) Andrea Wendrow (b) (4)	05 Sep 2020 16:07:09

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:50:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:49
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	05 Sep 2020 16:07:09

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:50:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:49
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4), (b) (6)	04 Mar 2021 11:12:22
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered with 'stop date is the date the IUD was removed' (Site from System).	Diana Bahena (b) (4)	02 Mar 2021 17:39:48
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	01 Mar 2021 19:13:26
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
User closed query 'Per CDM: Please consider updating frequency field to a length of time.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 10:31:54
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	11 Sep 2020 20:56:18
Query 'Per CDM: Please consider updating frequency field to a length of time.' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4)	11 Sep 2020 20:56:07
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	11 Sep 2020 20:55:51
User entered 'once (ONCE)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	11 Sep 2020 20:55:51
User opened query 'Per CDM: Please consider updating frequency field to a length of time.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 18:12:50
User entered 'other (OTHER)'	Andrea Wendrow (b) (4)	05 Sep 2020 16:07:09

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:50:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:49
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	11 Sep 2020 20:56:18
	(b) (4)	
User entered 'intrauterine device continuous dosing'	Andrea Wendrow (b) (4)	05 Sep 2020 16:07:09
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:50:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:49
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Other (OTHER)'	(b) (4) Andrea Wendrow (b) (4)	05 Sep 2020 16:07:09

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:50:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:49
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'intrauterine'	(b) (4) Andrea Wendrow (b) (4)	05 Sep 2020 16:07:09

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:49
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'UN UNK 2014'	(b) (4) Andrea Wendrow (b) (4)	05 Sep 2020 16:07:09

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:50:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:49
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	05 Sep 2020 16:07:09

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:50:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:49
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:40:44
	(b) (4)	
Signature has been broken.	Nia Moragne-O'Neal	01 Mar 2021 19:13:26
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Nia Moragne-O'Neal	01 Mar 2021 19:13:26
	(b) (4)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	05 Sep 2020 16:07:09
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:49
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:40:44
Signature has been broken.	Nia Moragne-O'Neal	01 Mar 2021 19:13:26
User entered '22 Feb 2021' reason for change: New Information	Nia Moragne-O'Neal	01 Mar 2021 19:13:26
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered empty.	Andrea Wendrow (b) (4)	05 Sep 2020 16:07:09

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:50:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:49
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4)	05 Sep 2020 16:07:09

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:50:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:49
User entered empty.	(b) (4), (b) (6) System	05 Sep 2020 16:07:09

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:50:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:49
User entered empty.	(b) (4), (b) (6) System	05 Sep 2020 16:07:09

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:50:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:49
User entered empty.	(b) (4), (b) (6) System	05 Sep 2020 16:07:09

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:50:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:52
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	07 Apr 2021 18:33:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 18:33:07
Data point term sent to Coder Coding entries removed.	System Marla Schwarber (b) (4)	07 Apr 2021 18:31:58 07 Apr 2021 18:31:24
User signature succeeded.	(b) (4) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Sep 2020 16:09:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 16:09:39
Data point term sent to Coder User entered 'ibuprofen'	System Andrea Wendrow (b) (4)	05 Sep 2020 16:09:03 05 Sep 2020 16:08:58

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:50:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:52
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4)	05 Sep 2020 16:08:58

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:50:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:52
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:37
	(b) (4)	
Signature has been broken.	Marla Schwarber (b) (4)	07 Apr 2021 18:31:24
	(b) (4)	
User entered 'Injection site pain' reason for change:	Marla Schwarber (b) (4)	07 Apr 2021 18:31:24
Data Entry Error	(b) (4)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'headache'	Andrea Wendrow (b) (4)	05 Sep 2020 16:08:58
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:50:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:52
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '600'	(b) (4) Andrea Wendrow (b) (4)	05 Sep 2020 16:08:58

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:50:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:52
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'mg (mg)'	(b) (4) Andrea Wendrow (b) (4)	05 Sep 2020 16:08:58

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:50:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:52
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	05 Sep 2020 16:08:58
	(b) (4)	

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:50:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:52
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'as needed (PRN)'	(b) (4) Andrea Wendrow (b) (4)	05 Sep 2020 16:08:58

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:50:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:52
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	05 Sep 2020 16:08:58

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:50:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:52
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Oral (ORAL)'	(b) (4) Andrea Wendrow (b) (4)	05 Sep 2020 16:08:58

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:50:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:52
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	05 Sep 2020 16:08:58
	(b) (4)	

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:52
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '05 Sep 2020'	(b) (4) Andrea Wendrow (b) (4)	05 Sep 2020 16:08:58

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:50:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:52
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	05 Sep 2020 16:08:58

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:50:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:52
User signature succeeded.	(b) (4), (b) (6)	
	Richard Novak (b) (4)	15 Feb 2021 03:35:51
User closed query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4)	
Query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' answered with 'resolution date entered' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 11:45:50
Query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' answered with 'resolution date entered' (Site from DM).	Michelle Agnoli (b) (4)	23 Oct 2020 19:15:13
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Michelle Agnoli (b) (4)	23 Oct 2020 19:15:03
	(b) (4)	
User opened query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:46:46
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	05 Sep 2020 16:08:58
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:52
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered '05 Sep 2020' reason for change: Per Query Resolution	Michelle Agnoli (b) (4)	23 Oct 2020 19:15:03
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	05 Sep 2020 16:08:58
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:50:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:52
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:37
	(b) (4)	
Signature has been broken.	Marla Schwarber (b) (4)	07 Apr 2021 18:31:24
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Marla Schwarber (b) (4)	07 Apr 2021 18:31:24
	(b) (4)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'No (N)'	Andrea Wendrow (b) (4)	05 Sep 2020 16:08:58
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:50:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:52
User entered empty.	(b) (4), (b) (6) System	05 Sep 2020 16:08:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:50:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:52
User entered empty.	(b) (4), (b) (6) System	05 Sep 2020 16:08:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:50:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:52
User entered empty.	(b) (4), (b) (6) System	05 Sep 2020 16:08:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:50:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:55
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Oct 2020 16:07:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:07:36
Data point term sent to Coder	System	15 Oct 2020 15:49:49
User entered 'ibuprofen'	Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:49:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:50:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:55
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'No (N)'	(b) (4) Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:49:12

US3492061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:50:42

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:55
User closed query 'Per DM CLR-RQ: Response noted. However, please re-review if AE reporting criteria per protocol 8.3.4 has been met. If yes, update to record indication as adverse event. If no, confirm that "PAIN AT INJECTION SITE DID NOT MEET AE REPORTING CRITERIA" in query response. Update as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:23:10
Query 'Per DM CLR-RQ: Response noted. However, please re-review if AE reporting criteria per protocol 8.3.4 has been met. If yes, update to record indication as adverse event. If no, confirm that "PAIN AT INJECTION SITE DID NOT MEET AE REPORTING CRITERIA" in query response. Update as appropriate. Otherwise, clarify. ' answered with "'PAIN AT INJECTION SITE DID NOT MEET AE REPORTING CRITERIA"' (Site from DM).	Diana Bahena (b) (4)	02 Mar 2021 17:40:40
User opened query 'Per DM CLR-RQ: Response noted. However, please re-review if AE reporting criteria per protocol 8.3.4 has been met. If yes, update to record indication as adverse event. If no, confirm that "PAIN AT INJECTION SITE DID NOT MEET AE REPORTING CRITERIA" in query response. Update as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 08:06:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
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)	02 Dec 2020 12:49:56
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'AE not necessary. Medicated during reactogenicity period for solicited symptoms, as per participant.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 15:43:57

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:50:42

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. 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)	01 Dec 2020 07:18:37
User entered 'pain at injection site'	Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:49:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:50:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:55
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '400'	(b) (4) Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:49:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:50:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:55
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'mg (mg)'	(b) (4) Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:49:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:50:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:55
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered empty.	(b) (4) Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:49:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:50:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:55
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'once daily (QD)'	(b) (4) Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:49:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:50:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:55
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered empty.	(b) (4) Lorna Sanchez McCann	15 Oct 2020 15:49:12
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:50:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:55
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Oral (ORAL)'	(b) (4) Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:49:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:50:42

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:55
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered empty.	(b) (4) Lorna Sanchez McCann	15 Oct 2020 15:49:12
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:50:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:55
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:40:44
	(b) (4)	
User entered '6 Oct 2020' reason for change: Per Query Resolution	Michelle Agnoli (b) (4)	19 Feb 2021 22:17:36
	(b) (4)	
Signature has been broken.	Michelle Agnoli (b) (4)	19 Feb 2021 22:16:07
	(b) (4)	
User entered '7 Oct 2020' reason for change: Per Query Resolution	Michelle Agnoli (b) (4)	19 Feb 2021 22:16:07
	(b) (4)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered '8 Oct 2020'	Lorna Sanchez McCann	15 Oct 2020 15:49:12
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:50:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:55
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered '0'	(b) (4) Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:49:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:50:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:55
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'No (N)'	(b) (4) Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:49:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:50:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:55
User signature succeeded.	(b) (4), (b) (6)	
	Richard Novak (b) (4)	26 Mar 2021 01:40:44
Signature has been broken.	(b) (4)	
	Michelle Agnoli (b) (4)	19 Feb 2021 22:18:13
	(b) (4)	
User entered '7 Oct 2020' reason for change: Per Query Resolution	Michelle Agnoli (b) (4)	19 Feb 2021 22:18:13
	(b) (4)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered '8 Oct 2020'	Lorna Sanchez McCann	15 Oct 2020 15:49:12
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:50:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:55
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:35:51
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann	15 Oct 2020 15:49:12
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:50:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:55
User entered '1'	(b) (4), (b) (6) System	15 Oct 2020 15:49:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:50:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:55
User entered '1'	(b) (4), (b) (6) System	15 Oct 2020 15:49:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:50:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:53:55
User entered '804 (804)'	(b) (4), (b) (6) System	15 Oct 2020 15:49:12

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:50:42

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:35:51
	(b) (4)	
User entered 'No (N)'	Nusirat Williams (b) (4)	05 Oct 2020 21:30:30
	(b) (4)	